EXHIBIT M

THIS EXHIBIT CONTAINS CONFIDENTIAL OR RESTRICTED CONFIDENTIAL INFORMATION AND HAS BEEN SERVED VIA EMAIL.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	)	MDL NO. 2875
THIS DOCUMENT RELATES TO:	)	HON. ROBERT B. KUGLER
ALL ACTIONS	)	

Monday, October 4, 2021

CONFIDENTIAL INFORMATION
SUBJECT TO PROTECTIVE ORDER

Remote Video-Recorded Oral Deposition of GEORGE JOHNSON, Ph.D. held at the location of the witness commencing at 9:07 a.m. BST on the above date, before Michael E. Miller, Fellow of the Academy of Professional Reporters, Certified Court Reporter, Registered Diplomate Reporter, Certified Realtime Reporter, and New Jersey Certified Court Reporter No. 30XI00242200.

GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

Page 2

REMOTE APPEARANCES:
MARTIN HARDING & MAZZOTTI LLP
BY: ROSEMARIE RIDDELL BOGDAN, ESQUIRE
rosemarie.bogdan@1800law1010.com
NICOLE HADDADNIA, ESQUIRE
nicole.haddadnia@1800law1010.com
1 Wall Street
Post Office Box 15141
Albany, New York 12212
(518)862-1200
Counsel for Plaintiffs

GOLDENBERGLAW
BY: MARLENE GOLDENBERG, ESQUIRE
mjgoldenberg@goldenberglaw.com
(present with The Witness)
800 Lasalle Avenue
Suite 2150
Minneapolis, Minnesota 55402
(616)333-4662
Counsel for Plaintiffs

LEVIN PAPANTONIO RAFFERTY PROCTOR BUCHANAN O'BRIEN BARR MOUGEY PA
BY: DANIEL A. NIGH, ESQUIRE
dnigh@levinlaw.com
316 South Baylen Street
Suite 600
Pensacola, Florida 32502
(850)435-7000
Counsel for Plaintiffs

HOLLIS LAW FIRM
BY: C. BRETT VAUGHN, ESQUIRE
brett@hollislawfirm.com
8101 College Boulevard
Overland Park, Kansas 66210
(913) 385-5400
Counsel for Plaintiffs

Page 3

REMOTE APPEARANCES:
GREENBERG TRAURIG LLP
BY: VICTORIA DAVIS LOCKARD, ESQUIRE
lockardv@gtlaw.com
(present with The Witness)
STEVEN M. HARKINS, ESQUIRE
harkinss@gtlaw.com
TARYN HARPER, ESQUIRE
harpert@gtlaw.com
Terminus 200
3333 Piedmont Road NE, Suite 2500
Atlanta, Georgia 30305
(678)553-2100
Counsel for Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA Inc., Actavis LLC, and Actavis Pharma Inc.

GREENBERG TRAURIG LLP
BY: STEPHEN T. FOWLER, ESQUIRE
fowlerst@gtlaw.com
(present with The Witness)
2101 L Street NW
Suite 1000
Washington, D.C. 20037
(202)331-1000
Counsel for Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA Inc., Actavis LLC, and Actavis Pharma Inc.

WALSH PIZZI O'REILLY FALANGA LLP
BY: CHRISTINE I. GANNON, ESQUIRE
cgannon@walsh.law
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973)757-1017
Counsel for Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA Inc., Actavis LLC, and Actavis Pharma Inc.

Page 4

REMOTE APPEARANCES:
BARNES & THORNBURG LLP
BY: KARA KAPKE, ESQUIRE
kara kapke@btlaw.com
11 South Meridian Street
Indianapolis, Indiana 46204
(317)236-1313
Counsel for CVS Pharmacy Inc. and Rite Aid Corporation

CIPRIANI & WERNER PC
BY: JILL H. FERTEL, ESQUIRE
jfertel@c-wlaw.com
450 Sentry Parkway
Suite 200
Blue Bell, Pennsylvania 19422
(610)567-0700
Counsel for Aurobindo Pharma USA Inc. and Aurolife Pharma LLC

FALKENBERG IVES LLP
BY: MEGAN A. ZMICK, ESQUIRE
maz@falkenbergives.com
230 West Monroe Street
Suite 2220
Chicago, Illinois 60606
(312)566-4801
Counsel for Humana Pharmacy Inc.

DUANE MORRIS LLP
BY: FREDERICK R. BALL, ESQUIRE
frball@duanemorris.com
100 High Street
Suite 200
Boston, Massachusetts 02110
(857)488-4200
Counsel for Zhejiang Huahai Pharmaceutical Co., Ltd.; Prinston Pharmaceutical Inc.; Huahai U.S. Inc.; and Solco Healthcare U.S., LLC

Page 5

REMOTE APPEARANCES:
BUCHANAN INGERSOLL & ROONEY PC
BY: ASHLEY D. JONES, ESQUIRE
ashley.jones@bipc.com
1700 K Street NW
Suite 300
Washington, D.C. 20006
(202) 452-7900
Counsel for Alberston's LLC

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI LLP
BY: FRANK H. STOY, ESQUIRE
fhstoy@pietragallo.com
One Oxford Centre
38th Floor
Pittsburgh, Pennsylvania 15219
(412)263-1840
Counsel for Mylan Pharmaceuticals Inc.

ALSO PRESENT:
MELISHA VALENZUELA
Hollis Law Firm

TRIAL TECHNICIAN:
CHRIS RITONA
Precision Trial Inc.

VIDEOGRAPHER:
JOSEPH VINER
Golkow Litigation Services
(present with The Witness)

INDEX

GEORGE JOHNSON, Ph.D.

October 4, 2021

DEPOSITION EXHIBITS

DEPOSITION EXHIBITS

DEPOSITION EXHIBITS

P R O C E E D I N G S

October 4, 2021, 9:07 a.m. BST

THE VIDEOGRAPHER: We're now on the record. My name is Joseph Viner. I'm a videographer from Golkow Litigation Services.

Today's date is October 4th, 2021, and the time is 9:07 a.m.

This video deposition is being held in London, U.K., in the matter of Valsartan, Losartan and Irbesartan Products Liability Litigation in the United States District Court of New Jersey.

The deponent is Dr. George Johnson.

The court reporter today is Mike Miller, and will now swear in the witness.

///

///

///

GEORGE JOHNSON, Ph.D., having been duly sworn, testified as follows:

EXAMINATION

BY MS. BOGDAN:

Q. Good morning, Dr. Johnson. My name is Rosemarie Bogdan, and I'm going to be asking you some questions today. I represent the plaintiffs in the action that has been commenced.

Have you had your deposition taken before?

A. I have not.

Q. Okay. In any capacity, in any litigation, this is the first time?

A. This is the first time.

Q. Okay. So since it is your first time giving a deposition, one thing that I would ask, and I'm sure the court reporter would ask, is that you wait until I'm done asking my question before you begin

to answer. That way the record can be clear. We can't speak at the same time, okay?

A. That's okay. Thank you for the advice, okay.

Q. And doing this by Zoom, sometimes there's a little delay with the connection, so to speak, so we have to be really cognizant of that. I think we'll notice if there is a delay as we go on this morning, and then we'll have to obviously accommodate it if there is.

If you don't understand a question that I ask, please let me know so I have the opportunity to rephrase it for you.

A. Understood.

Q. If you answer a question, I'm going to assume you understood it, so if you don't understand what I'm asking, please let me know that, okay?

A. Okay.

Q. Now, did you meet with the attorneys for the defendants prior to today?

A. Yes, I did.

Q. When did you meet with them?

MS. LOCKARD: Did you say when or where?

MS. BOGDAN: When.

MS. LOCKARD: Sorry, I couldn't hear.

A. When? We met -- I'll have to look at that. We had an official meeting yesterday and the day before, and we arrived day before that. Is that correct?

BY MS. BOGDAN:

Q. Okay. And how many hours did you spend with the defense counsel?

A. During this current trip?

Q. Yes.

A. During this current trip, I would say over the four days, including today, it would be about 40 hours. We've been spending a lot of time. That's including my time as well.

Q. And when you say 40 -- you said four-zero, 40 hours?

A. That's including my work on this -- on this project as well as our meetings together.

Q. And so what were the hours of your meetings together in the last few days?
A. In the last few days, we spent -- we met yesterday at their office in Greenberg Traurig from 10:30 until 4:00, and the previous day was 11:00 until 5:00.
Q. Now, did you spend time on your own preparing for the deposition?
A. Yes, I did.
Q. And how many hours did you spend preparing for the deposition on your own?
A. On my own? During this trip or altogether?
Q. During this trip.
A. During this trip. On top of that, I spent an additional maybe 4 hours both of those days, and the previous day, I would say 10 hours preparing, reading everything. I like to prepare for things, so lots of reading.
Q. And what materials or documents did you review to prepare for the deposition?
A. The recent documents that I've

been looking at are the depositions from the other expert witnesses. I've spent a lot of time on those. I've refreshed my memory of my own publication, of my own report. So those have been the big ones.
And then critiquing some of the key publications which support or which I critique in my report as well, so mainly those ones.
Q. Did you keep note of the key publications that you reviewed to prepare for your testimony today, meaning the identity of them?
A. They're all contained within the list that you have.
Q. I'm asking specifically which ones they are.
A. I did not keep a list of those.
Q. Do you have a list in your mind of the publications or studies that you view as key publications in this case?
A. In my mind is my 2021 publication around this topic. Another one would be the Peto study on the cancer

bioassay dose response. Another one would be the OECD guideline and the cancer bioassay, and then I tried to keep up to date, so the most recent expert witness depositions would be the key ones I've been looking at over the last few days.
Q. Okay. I did pick up that you mentioned the Peto study. I'm assuming you said Peto, P-E-T-O?
A. Correct.
Q. And then there was a second one that you mentioned that was -- mentioned the words "guideline" and "bioassay," but I don't believe I heard the author or the entity that did the study.
A. For the videographer, if you say it very slowly, OECD. They provide the guidelines for all genetic toxicity assays and cancer bioassays, and then they need to be abided to. So I revised those.
Q. So you're speaking of the guidelines?
A. Correct, the OECD guidelines.
Q. Now, who is in the room with

you there today?
A. Victoria Lockard, Steve Fowler. I heard the names --
THE WITNESS: But you're --
MS. GOLDENBERG: Marlene Goldenberg. I'm on Rosemarie's team.
THE WITNESS: Marlene Goldenberg. I know, but apologies.
A. And the videographer.
THE WITNESS: Apologies for not remembering your name as well.
MS. LOCKARD: Joe.
A. So did you get that? So there's four of us. Hopefully you've heard those names, and myself.
BY MS. BOGDAN:
Q. Do you have any documents with you today?
A. I do.
Q. Okay. What documents do you have with you today?
MS. LOCKARD: You can say what's in front of you.
A. What's in front of me is my

report and my publication and my CV, and we have boxes of the list of other relevant details that you have -- you have the list of, I think.

MS. LOCKARD: Those are my boxes.

THE WITNESS: Those are your boxes.

MS. LOCKARD: Counsel's boxes.

THE WITNESS: We have counsel's boxes too.

BY MS. BOGDAN:

Q. And the counsel boxes, they were not yours, right? That's not your records that you brought in as part of your file.

A. Correct.

Q. And then I'm assuming you just have the -- you have the videographer there and you have the Zoom open on a computer? I can't quite see the setup.

A. This might take a bit longer to explain. So we have the computer in front of me that I'm speaking to you on via Zoom. We

have the videographer at the end of the room with the camera to record everything. And that's why I keep looking, to ensure that during the video -- yeah. Is that enough detail?

Q. Yep, that's good.

Do you have any type of a cell phone there with you that you're interacting with?

A. I do not.

Q. Okay. And you're not interacting with the computer, correct?

A. Correct.

MS. BOGDAN: If we could pull up and mark as Exhibit 1 the notice to take the videotaped deposition of Dr. Johnson.

(Whereupon, Deposition Exhibit Johnson-1, Notice To Take Videotaped Oral Deposition, was marked for identification.)

MS. GOLDENBERG: Can you turn your camera on? It will be easier to see if you have any objections, but

the depo protocol does require that cameras be turned on for anybody else in the room.

MS. LOCKARD: Not if there's counsel in the room. That's for remote.

MS. GOLDENBERG: Rosemarie is remote.

MS. LOCKARD: I'll turn it on, but I don't agree that that's required.

I just put in front of Dr. Johnson a hard copy of his notice of video deposition, for the record.

BY MS. BOGDAN:

Q. Dr. Johnson, do you see that document that's been marked as Exhibit 1?

A. I see the document on Zoom, and I also have a hard copy.

Q. Have you seen that before?

A. As far as I can recall, I have, and I've seen many documents, but yes.

Q. Turning your attention to the third page of the exhibit, which is -- begins

with Exhibit A.

A. Okay. I can see it. Thank you.

Q. That requests certain documents be produced?

A. Yes, I can see this. And just to reconfirm, I definitely have seen this document.

Q. All right. And did you go about collecting the things that are itemized here on Exhibit A?

A. I did, and I'm confident with the list.

Q. So you produced all of your invoices and billing records for this matter?

A. Correct.

Q. With regard to the second itemized request, did you have any notes that you produced?

A. I did not.

Q. And you didn't have any notes to produce?

A. No. My understanding of this topic was included in the report, and there

was no notes surrounding that.
Q. So other than your report that you wrote, there are no other notes or summaries or any other writings that you took as part of your work in this matter?
MS. LOCKARD: Objection, asked and answered.
A. So my response again is: Correct, there are no additional notes.
BY MS. BOGDAN:
Q. And did you produce copies of all materials, documents and articles that you relied on for your opinions that you're providing in this matter?
A. Yes, that is correct.
Q. Are there any textbooks that you're relying on for your opinions in this matter?
A. There are no textbooks that I'm relying upon for my opinion, but I do read textbooks.
Q. I know you read textbooks, but I'm sorry, the connection is a little bit fuzzy. Did you say that there are no

textbooks you relied on?
A. There were no textbooks I'm relying on for my opinion presented in the report, but I do read textbooks.
Q. Now, did you prepare a report in this case?
A. I did prepare a report in this case.
Q. Do you have a copy of it there in front of you?
A. Yes, I do.
Q. And is that what was served as an amended report on October 1st, 2021?
A. As far as I'm aware, that's correct.
MS. BOGDAN: Can we please pull up the doctor's amended report and mark it as Exhibit 2.
(Whereupon, Deposition Exhibit Johnson-2, 10/1/21 Johnson Expert Report, was marked for identification.)
THE WITNESS: Apologies. Clarification. In this instance and

further instances, will this also appear in that additional link for me to look at in an online way, or do we rely on my hard copy? Thank you.
MS. LOCKARD: You need to be able to pull up the link and --
THE WITNESS: Is that this? Would I just go over to -- apologies for this.
TRIAL TECHNICIAN: No worries. Just remember you may need to hit F5 to refresh the browser to see the document.
THE WITNESS: Excellent. So it's Exhibit 2, after the refresh, I have that. Brilliant. And I have a hard copy. Thank you very much.
MS. BOGDAN: Have we marked that as Exhibit 2?
THE STENOGRAPHER: Yes.
BY MS. BOGDAN:
Q. Now, does that Exhibit 2 report contain all your opinions you intend to offer in this matter?

A. Not just my opinions in the report, but I have additional knowledge that may come out during this deposition, so it may not contain those opinions. But I'm very confident of all my opinions presented in this report.
Q. And when you say I may have additional knowledge that will come out during this deposition, what additional knowledge are you referring to?
MS. LOCKARD: Objection, form, vague, ambiguous.
A. We will see during the deposition, if there's a question that I can expound upon beyond that presented in my report, then I will do so.
BY MS. BOGDAN:
Q. Doctor, when you said additional knowledge, I was -- are you saying that because there's something that you know now that you have learned since authoring this report that you did not include that would further support your opinions?
A. That is not correct. I

included all of the information within that report, but during reading the depositions of other expert witnesses, I've critiqued further detail and realized that some of those opinions can be -- can be critiqued quite heavily based on my understanding, but not all of that is presented in this report.

Q. And which depositions of expert witnesses are you speaking to particularly?

A. I forget the name of the one I've quite recently -- where there was critique and a long explanation around the IARC findings that are very historical. I've read those and have additional information to critique and reject those obsolete -- that obsolete report.

Q. And what report are you referring to being obsolete?

A. I forget the date. I think it's in the '70s from the IARC, the International Agency for the Research of Cancer, I think. The IARC or a subset of the WHO, on NDMA.

Q. Are you referring to the 1978

monograph regarding NDMA published by IARC?

A. Yes.

Q. Any other critiques that you're aware of as you sit here today based upon reading of the deposition transcripts?

A. Not that I'm aware of today, but I've been working on this topic my whole career, and I will have additional information when asked.

Q. Now, the report that's in front of you that's been marked Exhibit 2, did you write that report yourself?

A. Yes, I did.

Q. Did you have the assistance of a graduate student or anyone -- did anyone assist you in writing it?

A. No, they did not.

Q. How much time did you spend writing the report?

A. Within the invoices, the report is discussed, so the invoices that cover reports within the statement cover it. And in addition to that, I've spent another approximately 130 hours since that last

invoice on this project, including this deposition preparation. So a subset of that time will be on preparation of that report.

Q. So there's an invoice for time that you have already spent that has not yet been prepared and sent to the defendants?

A. That is correct.

Q. Now, the amended report dated October 1st, 2021, what changes did you make in the report?

A. I cannot be clear on those changes at the current time.

Q. What prompted making those changes or serving an amended report?

A. They are typographical changes surrounding references where there was not complete references, so it was all around referencing to ensure that everyone had a precise list of references. That was the -- that was the changes. That was the amendments, as far as I understand. And I have -- I hope I've got a good memory, and that's how I remember it.

Q. Now, in the text of the report

itself, you have references which are primarily in the footnotes, correct?

A. Correct. I saw this as a good way of presenting the references.

Q. And then there's an Exhibit A to the report, which is your CV, correct?

A. I can see -- yeah, I can see my CV.

Q. Okay. Is that your most recent CV?

A. Correct. In addition to updating the report, I updated my CV with recent publications. I've been publishing a lot recently and wanted to ensure that you had seen those publications within my CV. So that was another amendment, to address that last question, as well.

Q. And then there's an Amended List of Materials Considered, correct?

A. As far as I'm aware, that's correct.

Q. Who prepared the Amended List of Materials Considered?

A. I prepared much of the

Page 30

information within that list, and the final list was prepared by GT.
THE WITNESS: Am I allowed to call them GT?
MS. LOCKARD: Sure.
THE WITNESS: Thank you.
BY MS. BOGDAN:
Q. GT, Greenberg Traurig?
A. Correct. Is it okay for me to say GT from here onwards?
Q. That's fine.
A. Thank you.
Q. As long as the record reflects what GT stands for, that's absolutely fine.
And what documents were added to the Amended List of Materials Considered?
A. I'm unaware of the exact details, and it would be the updated expert depositions and things of that effect.
Q. Did you read all of the expert deposition transcripts that are reflected?
A. I considered all of them and read in detail at least half of them.
Q. Can you tell me which ones you

Page 31

read in detail?
A. The -- my critique of the ones I read in detail is contained in my report, and the more recent ones are the ones related to my understanding of genetic toxicology, risk assessment and so on.
Q. I was looking for, Dr. Johnson, which of the deposition transcripts you read in detail, and they're reflected on page 1 of your Amended List of Materials Considered?
A. I do not have that list in front of me at the current time.
MS. LOCKARD: He does now. I just handed him the amended list.
A. I do now.
BY MS. BOGDAN:
Q. I believe also it's being displayed on the screen for you.
A. Oh. Sorry, I'm still on Golkow. Thank you. I've gone back to Zoom.
I now have the information in front of me, and I will --
MS. LOCKARD: There's no question pending.

Page 32

THE WITNESS: There's no question pending. Apologies. I now have that in front of me.
BY MS. BOGDAN:
Q. Okay. I do believe there was a question. What I asked was: Which of the deposition transcripts did you review in detail?
A. I've reviewed the transcript from Hecht. That was very good. I enjoyed reading that and had some critical understanding of that. Raphael Nudelman as well, and Panigrahy. Those are the ones that come to the forefront of my memory, but I've read other ones as well.
Q. Did you read all of them?
A. I opened all of them, but I read in detail the ones relevant to my area of expertise.
Q. On the -- when you say you opened them, what does that mean?
A. They were provided as PDFs, and I clicked open, and I would look through, see the topic. If it was not relevant to my

Page 33

report and my level of expertise, my area of expertise, then I would go on to another one.
Q. Did you add to your report critiques of the deposition testimony that you read?
A. I think my critiques were on the expert reports and not on the expert depositions, mainly due to timings of the report, because the depositions hadn't appeared at that time. So I was critiquing the reports and reflecting on that within my report. That's my understanding.
Q. Did you create any writings regarding your critiques of the deposition testimony?
A. I did not.
Q. Did you make any notes regarding your review of the deposition testimonies that you read?
A. I did not. My practice with this, observe comments and statements within the depositions that I agree with sometimes, and I think that's useful information to remember. If I disagree with it, I'll look

Page 34

into it, I'll research it by reading the up-to-date scientific knowledge around that topic, and come to my own understanding of whether I agree with that statement or not, with no notes. Just into my -- into my brain.

Q. Now, you mentioned that you reviewed Raphael Nudelman's deposition?

A. Yes. And I think that was -- we had feedback then. I think that was quite an early one, if I remember correctly.

Q. Do you know Raphael Nudelman?

A. I have met Raphael Nudelman. Should I tell the story of how I know him? No?

MS. LOCKARD: Just answer the question, Dr. Johnson. Listen to the question and answer the question, please.

A. I do know Raphael Nudelman. Since this issue started, I've met him since that time.

BY MS. BOGDAN:

Q. How did you first become

Page 35

acquainted with Raphael Nudelman?

A. I had looked into this topic on my own regard with some of my regulatory colleagues. I've prepared a PowerPoint presentation, and I've been invited to present this at an Informa Impurities conference in Berlin, and at that time I met Raphael Nudelman, I think over breakfast, and I saw his -- he'd seen my presentation, he was interested in my presentation, and I met him at that time.

[redacted]

Page 36

[redacted]

Q. Now, when you say colleagues, I'm not looking for the private health information with regard to whichever individual was on valsartan, but who did you speak with regarding this topic as far as your interest in it and wanting to learn more information about it?

A. So that small group that I discussed, we were all -- we're all risk assessment experts and genetic toxicology experts and cancer bioassay experts. We discussed it in depth with those colleagues.

I then opened it up to a group that I chair within the Health Environmental

Page 37

Science Institute based in Washington, D.C. that's a tripartite -- tripartite organization made up of regulatory bodies of industry, academics and consultants, and I presented it to that group.

And we -- and they -- I was doing the work. They were interested. They were helping with the adjustment factors within the PDE, critiquing it. I presented at Impurities conferences, which were made up of the same sort of people, industry, regulatory experts and so on.

And at that time, I had not been to many Impurities conferences, but since this was so relevant, I started getting invited to a lot of Impurities conferences, and at those times I was learning from the other speakers as well from their presentations, it was very good. I was becoming very up to date with the topic, and yeah, lots and lots of people.

This is my area of research for the last few years independently of this case, and I work with many different expert

Page 38

groups where this relates to our interest.
Q. Now, what were the names of -- you mentioned that there were several Health Canada colleagues that you spoke with. Who are they?
A. That's a confidential matter as far as I'm concerned.
Q. The names of the Health Canada colleagues that you spoke with regarding the issue with nitrosamine contamination in valsartan?
A. Yes.
Q. Why do you say that that's a confidential...
A. Because of the nature of this case.
MS. BOGDAN: I don't understand what privilege the witness is claiming. If he had conversations regarding this issue on the topic of nitrosamine contamination --
MS. LOCKARD: His position --
MS. BOGDAN: -- I just want to know --

Page 39

MS. LOCKARD: Yeah, his position on this is that he had discussions confidentially prior to being retained in this case with these agency individuals, and that discussion occurred with the understanding that it was confidential. So he's uncomfortable disclosing those names.
MS. BOGDAN: Well, I --
MS. LOCKARD: So I'll make an objection based on confidentiality, and, you know, if we need to discuss it off the record, we can do that.
THE WITNESS: That's correct, that is my position.
MS. BOGDAN: Well, it will be the plaintiffs' position that with regard to anyone that he spoke with particularly regarding this issue at the time that the recall became known, that that would be highly relevant to the issues posed here in this matter.
And certainly this deposition

Page 40

is not public information, and, you know, the identities of these individuals from the Health Canada agency would be relevant, highly pertinent and certainly discoverable.
BY MS. BOGDAN:
Q. Do you serve with any of these individuals in -- on any of the groups or committees that you've referenced in your earlier testimony?
A. That is correct. I work with some of these regulatory experts on sort of these expert groups.
Q. And which expert groups do you serve with these individuals on?
A. We've created with the experts on the question -- apologies. Wipe that. That didn't make sense.
I work with many of these experts on the Health Environmental Science Institute Genetic Toxicology Technical Committee, the HESI GTTC, and also on the upcoming IWGT, I think the expanded version of that is the International Workshop on

Page 41

Genetic Toxicology, and it's upcoming. It's supposed to be this year in Ottawa, and it's been delayed due to COVID to be next year.
MS. BOGDAN: If we could pull up the 2020 HESI Annual Report, please.
MS. LOCKARD: You'll have to use your link for that.
THE WITNESS: I'm just going to find it now on the Golkow.
(Whereupon, Deposition Exhibit Johnson-3, 2020 HESI Annual Report, was marked for identification.)
THE WITNESS: It has yet to appear on it, on Golkow.
MS. LOCKARD: Hit refresh.
THE WITNESS: I'm refreshing. Exhibit 3, is that correct?
TRIAL TECHNICIAN: That is correct.
THE WITNESS: Thank you.
BY MS. BOGDAN:
Q. Is this the organization that you were referring to, Dr. Johnson?

Page 42

A. I need a few seconds while the slow Internet catches up. It's still loading.
Q. Okay.
A. HESI Annual Report. Correct. A subset of HESI. They're made up of different expert groups, and the GTTC is one such group.
Q. What is HESI?
A. I've stated it in previous questions and I'll state it again. It's the Health Environmental Science Institute.
Q. What is its purpose?
A. My way of describing them is we find best practice or we find issues that relate to our expertise or we find blue-sky thinking of new approaches. We create an expert group, we critique that, and then we publish that and ensure the publish size and keep it all open. And then we educate as well through workshops and publications.
Q. What are the funding sources for HESI?
A. As a whole, they are -- so

Page 43

industry provides funds across the different industry bodies to HESI, and then there's subsets of that. A portion of funding goes to the expert groups, and those expert groups can use the funding for meetings.
Q. And when you say industry, what types of industries are you referring to?
A. It includes pharmaceutical companies, also contract research organizations, also -- I think we still have cosmetics companies, agrochemical companies, pet- -- not petrochemical companies at the current time, I do not think, but that may be incorrect.
So anyone that uses genetic toxicology within their day-to-day life. If there's a big company involved within that, then they would want to be a part of this expert committee.
Q. So HESI is funded by industry, which would be made up of pharmaceutical companies, chemical companies and other business entities?
A. That's how I understand their

Page 44

funding platform is.
Q. Are you an employee of HESI?
A. No. They do not pay me in any way. They pay for the meetings, but there's been no meetings since COVID. There's been online meeting technologies that may have cost some of the money, but the face-to-face meetings uses up the major proportion of that, and then some of the rest of the funding goes towards funding HESI staff to support our clerical needs. There's no money that goes to me.
Q. Does HESI fund research?
A. They have an ability to fund research. Those subgroups have an ability to use money, if there's surplus money, to fund research. It's not -- it's up to that committee.
Q. Have you done any research that was funded by HESI?
A. Not that I'm aware of. The reason for my delay is we've had funding -- it's usually been from Health Canada -- to support our project, and then we integrate

Page 45

that within the HESI group. So that's how I see it.
So we do projects within our group, and then they're always funded by Health Canada.
And if there's an example where I have been funded for HESI research, that would be my misunderstanding that it would be -- I think it's Health Canada.
My confident answer is no.
Q. And --
A. Apologies. I would definitely not be the PI if that was the case anyway. Sorry.
Q. And when you say PI, are you referring to principal investigator?
A. Exactly that term.
Q. So which of the committees are you affiliated with with HESI? Would that be the genetic toxicology group?
A. Yes, that would be the one.
Q. And what role do you have with the genetic toxicology group?
A. There's a subgroup called the

Page 46

quantitative subgroup, where we address exactly the issue we're discussing today, and I chair that. I cochair that with another member. He's currently from Hoffman-La Roche, Andreas Zeller, and previously it was someone from Health Canada. And yeah, it's usually -- so that's my role within there.

And when you're a chair of a subgroup, you become on the steering group of the GTTC.

Q. And GCC [sic] stands for?

A. GTTC stands for Genetic Toxicology Technical Committee, as far as I'm aware.

Q. So for the transcript, that should be GTTC, correct --

A. Correct.

Q. -- not GCC? Okay, that makes sense.

A. Cool.

Q. And who is on the subgroup with you?

A. It's a big subgroup. There's

Page 47

different levels of membership. There's interested parties, and that includes many regulators, many industry experts, many academics, many consultants. Then there's an active -- more active work group, that would include myself, Paul White from Health Canada, and Andreas Zeller, and we do a large proportion of the work and present that to the wider group, who are very interested in this topic and have opinions but have less time to put into it because this is our research area of expertise.

Q. Now, does this organization collect committee dues? Are there dues that people have to pay to belong?

A. My understanding of the funding is the HESI bigger committee takes an annual fee from the company, and then they pay a certain amount to become a part of a group such as the GTTC. That's my understanding of the funding.

Q. So the members pay a fee to HESI to belong to the organization?

A. The industry groups are

Page 48

requested for that. The consultants, the academics and the regulatory bodies are not requested that funding, as far as I'm aware.

Q. What is the cost for an industry -- when you say industry group, are you referring to individual companies?

A. I am referring to individual companies.

Q. And what is the fee for an individual company to join HESI in a given year?

A. I do not want to say an incorrect number. Because I'm not a company, I don't know the exact number.

Q. If we could move to page 33 of this exhibit, which should have Genetic Toxicology. And when I say 33, I mean the numbered page 33. There we go.

A. I'm almost there.

Q. And, Doctor, let me know once you have that loaded on the screen.

A. With the top word being "Genetic Toxicology" and then "Our Mission"; is that correct?

Page 49

Q. Yes.

A. Excellent. Thank you. I have that in front of me.

Q. Okay. Is that the group to which you belong?

A. Yes.

Q. And then if we could move to page 35, please.

A. Yeah, I can see that too.

Q. Okay. Great.

Under In Progress at the top of the page, in the third sentence, could you read that, please, beginning with "Permitted"?

A. Permitted daily exposure limits for noteworthy mutagenic nitrosamines. And this entirely links to my publication, which was a HESI publication.

Q. And when you say links to, so this is referencing a publication that you were actually involved with, correct?

A. Correct.

Q. And when was that publication published?

Page 50

A. I'm reaching to get it because the exact date could be useful. It was received 1st of March 2021 and accepted 11th of May 2021.
Q. So that was actually referencing that publication that you had underway in 2020?
A. Yes, and as I mentioned previously, it was underway at the time of my presentation in Berlin too, just the research around it.
Q. And are you referring to the 2018 presentation in Berlin?
A. Correct.
Q. And who did you attend -- or you actually spoke at the 2018 --
A. I think --
Q. -- Berlin presentation or did you just attend?
(Clarification requested by the stenographer.)
THE WITNESS: Berlin Informa.
BY MS. BOGDAN:
Q. And what was the name of that

Page 51

seminar?
A. I've attended many seminars. The Informa seminars would have Informa Impurities. The focus is on impurities within that seminar.
Q. Who was the sponsor of that seminar?
A. I do not know. Informa were the people running it.
Q. Is Informa the name of the company or the administrative group that runs seminars?
A. My understanding is the administrative group that runs seminars.
Q. Who spoke with you at that seminar?
A. I cannot recall exactly. My answer would be that's where I met Raphael Nudelman, as I've previously stated in my dep, due to a previous question; and Andrew Teasdale presented as well. He's a leading expert in impurities. And beyond that, I couldn't recall any other names. That was my first Impurities conference, and I was yet to

Page 52

know who the leading experts in that area were.
Q. And who did Raphael Nudelman work for at the time, if anyone, in 2018 when you first met him?
A. It was my understanding that he worked for Teva.
Q. Does he still work for Teva, to your understanding?
A. I think he does, yes. I'm confident that he does.
Q. And Andrew Teasdale, what company does he work for?
A. He works for AstraZeneca, and he's on many, many expert groups on this topic.
Q. And what prompted the holding of this conference in Berlin in 2018?
MS. LOCKARD: Objection, form, speculation.
You can answer.
THE WITNESS: I can answer?
A. Informa, from my recollection and understanding, have been running

Page 53

Impurities conferences for many years, and as an expert, as a group of scientists and people working on topics, you always present the newest topic under consideration at that time. So that would have been the reason for detailing on this topic.
BY MS. BOGDAN:
Q. Had the recalls or the issue with nitrosamine contamination in valsartan come to the forefront before this meeting took place?
MS. LOCKARD: Objection, compound, vague.
A. I'm unaware of that.
BY MS. BOGDAN:
Q. Were valsartan recalls part of the topic that was addressed at this Berlin conference in 2018?
A. The topic, potentially, instructions would mention the reason for our focus on this topic. The science was the focus of the topic. It was mostly to do with the structural activity relationship experts, so I was in the room for the chemists talking

Page 54

about chemistry, and I was the toxicologist. So we talked about the science, but there would have been introductory information as well.

Q. Did this conference take place after it became known that NDMA was in valsartan?

MS. LOCKARD: Objection, form, vague.

A. My understanding -- I do not know the answer to that.

BY MS. BOGDAN:

Q. What did you speak on at this conference?

A. It was very similar to my publication and aspects of my report, which is more detailed and focused risk assessment of this exploratory paper.

So it was on the first steps in producing the paper, so it was to show that NDMA, and potentially I think I talked to NDEA at that time, were mutagenic substances with very clear mutation spectrum, with very clear DNA adducts, with very clear

Page 55

understanding about DNA repair, and that's been my area of expertise for many years.

So I introduced that in some slides, and then I showed with that understanding you can carry out permitted daily exposure according to the ICH guidance, and I carried out a permitted daily exposure with some of the data available to me.

Q. Did this conference take place in June of 2018?

A. Potentially.

Q. And when was the conference originally scheduled to take place, as far -- excuse me.

When was the date of the conference set?

A. I do not know.

Q. When were you invited to speak at the conference?

A. I do not know.

Q. Were you invited to speak at the conference more than a month before it took place?

A. I do not know. I've presented

Page 56

at many of these conferences.

Q. Do you have any -- did you present any written materials at the conference?

A. I presented a slide set which I spoke to.

Q. So a PowerPoint-type presentation?

A. Yes.

Q. Do you still have that?

A. I'm unaware if I do.

Q. Did anyone at the conference speak specifically about NDMA or NDEA in valsartan?

A. Andrew Teasdale presented the issue at hand and the reason, the chemical reason for NDMA in this instance.

Q. And who does Andrew Teasdale -- or who did he work for at the time?

MS. LOCKARD: Objection, asked and answered.

MS. BOGDAN: I remember the doctor saying Raphael Nudelman worked for Teva.

Page 57

BY MS. BOGDAN:

Q. Who did Andrew Teasdale work for?

MS. LOCKARD: Objection, asked and answered.

A. As stated previously, Andrew Teasdale works for AstraZeneca and did at that time, and he's also party to numerous expert groups, including the official ones which talk with the regulatory bodies.

BY MS. BOGDAN:

Q. How many speakers presented at this conference in Berlin?

A. I do not know.

Q. Was it one day of presentations or more than one day?

A. I do not know. At an estimate, two days.

Q. Did you go with anyone to the conference?

A. No, I did not. I went to Berlin by myself. It was exciting.

Q. If we could go back to the exhibit, same page, 35.

A. This was the HESI document?
Q. Yes.
A. Okay.
Q. And if we could go to Participating Organizations.
A. Participate -- on page 35?
Q. Yeah. And if we could go to Academic/Research Institutes.
A. Yep. I'm there, yes.
Q. Is the university that you work for listed?
A. Yes. I work for Swansea University.
Q. And how long have you worked for Swansea?
A. I carried out my Ph.D. from 2002 to 2006, at which time I did some demonstrating, so I think I got paid at that time. The 2007 period, I had a postdoctoral research project on dose response in another set of compounds that were not nitrosamines.
Then I got a job as a tutor, which is a teaching role, and I had research ability at that time. And then I worked my

way through the grades to where I am today.
So that's the time -- the time frame.
Q. And when you say worked my way through the grades to where I am today, where are you today?
A. I'm an associate professor; that's one down from professor in the university -- in the U.K. university career grades.
Q. Are you on track to become a professor?
A. Yes, very close to becoming professor.
Q. If we could go back to page 35 and look at Industry, please, which is right under Academic/Research Institutions?
A. Not that I am looking -- I'm not looking at Zoom, but I have it in front of me. Thank you.
Q. And do you recognize the names of the companies listed?
A. I do recognize them, yes.
Q. And this list of companies is

affiliated with the Genetic Toxicology Committee?
A. Yes, correct.
Q. Could you please read the names of the companies and tell me what type of business they're in?
MS. LOCKARD: Objection.
BY MS. BOGDAN:
Q. If you know.
MS. LOCKARD: Vague.
BY MS. BOGDAN:
Q. Well, we can go one by one then. The first company listed is AbbVie.
Do you see that?
A. I see AbbVie. I --
Q. What is -- what is the business of AbbVie?
A. I do not know. I think they may have a pharmaceutical wing, but I'm not confident in that statement.
Q. The next company is Amgen.
Do you see that?
A. I see that, and it would be the same answer. They may have a pharmaceutical

wing, but I do not know.
Q. Do you know any other type of business Amgen is involved in?
A. I -- I do not, no.
Q. Are they a chemical company?
A. I repeat myself. I do not know.
Q. The next company name, AstraZeneca, what type of company is AstraZeneca?
A. Pharmaceutical company.
Q. The next company, BASF, what type of business do they have?
A. Chemical company.
Q. The next company, Boehringer Ingelheim, what type of company is that?
MS. LOCKARD: Objection, vague.
BY MS. BOGDAN:
Q. What is the business of Boehringer Ingelheim?
A. I know -- I think they have a pharmaceutical wing and they may do other business as well.
Q. The next company, Bristol Myers

Page 62

Squibb Company, what is their business, if you know?
A. Again, I think they have a pharmaceutical wing and a focus on pharmaceuticals. I'm unaware of their other business.
Q. The next company listed, Charles River Laboratories. What is the business of Charles River Laboratories?
A. Charles River are a leading contract research organization to which industry and government regulatory bodies get a lot of their work carried out, so lots of the genetic toxicology-type approaches and cancer bioassays.
Q. And they actually do testing and laboratory-type work?
A. Correct, on a very large scale.
Q. The next company, Corteva Agriscience, what is the business of Corteva Agriscience?
A. I do not know, but from the second word, I would assume some agrochemical links.

Page 63

Q. Covance, do you see that company listed?
A. I do. I see -- apologies.
Q. No, we just have a little bit of delay. I apologize as well. I'm not trying to speak over you, and I know you're not trying to speak over me.
What is the business of Covance?
A. Covance are in the same industrial field as Charles River and carry out a lot of the genetic toxicology, cancer bioassay work and clinical trials work for everyone, including industry and regulatory bodies and academics, if they wish. It's a contract research organization.
Q. The next company, Denali Therapeutics, what is the business of Denali?
A. I do not know Denali, but from therapeutics, they should be in the business of therapeutics.
Q. The next company, the Dow Chemical Company, what is the business of Dow Chemical Company?

Page 64

A. The Dow Chemical Company are a chemical company.
Q. Yeah.
The next company listed, Eli Lilly and Company, what is the business of Eli Lilly?
A. I think, again, that they have a pharmaceutical wing and some focus, and potentially they'll do other business. That's -- that's my understanding.
Q. The next company, Genentech, what is the business of Genentech?
A. Again, I don't have a clear understanding of their -- of their work.
Q. The next company, Gentronix, what is the work of Gentronix?
A. Gentronix are an up-and-coming contract research organization, and in addition to carrying out the CRO work, the contract research organization work, for industry, and also for regulatory bodies and so on, and government research bodies and all those guys, they also have some inventions of their own test systems too.

Page 65

Q. The next company listed, GlaxoSmithKline, what is the business of GlaxoSmithKline?
A. I'm confident that they have a pharmaceutical wing and they change their profiles quite a lot, but used to make some food as well, I think.
Q. The next entity, Helix3 Inc., what is the business of Helix3 Inc.?
A. From my understanding, I think they're a contract research organization, again, a small one, using novel approaches, but again, doing this work for industry and for government regulatory bodies and anyone such as NIH who wishes to outsource any experimental work.
Q. The next company, Janssen Pharmaceuticals, is that a pharmaceutical company to your knowledge?
A. Janssen Pharmaceuticals is a subset of Johnson & Johnson, and this is their pharmaceutical wing.
Q. The next company, Litron Laboratories, are you familiar with that

Page 66

company?
A. Yes, very familiar with Litron Laboratories. You'll see from my publications, I work with them on science a lot. They are a CRO, contract research organization, and they also carry out a lot of inventive, patented assay development work, and they're very well regarded as well. So again, a CRO.
Q. When you say a contract research organization, that means they can be contracted by a third party to do research, correct?
A. They can, but usually it's less research and more mandated assays, including the genetic toxicology assays that would go towards submissions or to hazard and risk assessments by the regulatory body themselves.
Q. So they do more testing?
A. Contract research organization, the focus would be on testing, and the companies and regulatory bodies would outsource that work for these bodies to do

Page 67

their testing, all in accordance with OECD guidelines.
Q. The next company, L'Oreal Corporation, is that -- (audio malfunction) --
(Clarification requested by the stenographer.)
BY MS. BOGDAN:
Q. Is that a cosmetic company?
A. According to my understanding, they focus on cosmetics.
Q. The next company, Merck & Company, what is the business of Merck?
A. I would like to take this one and the next one together. I'm aware that there's two Mercks, and I think they both have a focus on pharmaceuticals. And one is more European and one is more American, and I don't know which one is which.
Q. The next company, MilliporeSigma, what is the business of MilliporeSigma?
A. MilliporeSigma are a huge company. They -- we use them a lot in

Page 68

laboratory research to buy consumables and so on for tissue culture and buy the chemicals for the testing. They're such a big company, they may have other wings as well, but from my understanding of Sigma is they produce a lot of scientific reagents.
Q. And the next company, Novartis, what is the business of Novartis?
A. Novartis, I'm quite confident they're focused on pharmaceuticals entirely, I think.
Q. The next company, Pfizer Inc., what's the business of Pfizer?
A. Again, Pfizer are a very large pharmaceutical company.
Q. The next company listed is Procter & Gamble Company. What is the business of Procter & Gamble?
A. My understanding of Procter & Gamble is the focus is on cosmetics, and I think they've got some food and nutraceuticals and products along those lines, but I don't think there's a focus on pharmaceuticals as such.

Page 69

Q. The next company listed, Roche, what is the business of Roche?
A. Roche are a pharmaceutical company, and I think they produce equipment as well for research, such as PCRs and such.
Q. The next company, Sanofi, what is the business of Sanofi?
A. I think they're a pharmaceutical company.
Q. And the next company, Syngenta, what is the business of Syngenta?
A. I think they're an agrochemical company, but I may need to be corrected.
Q. The next company, Takeda Pharmaceutical Company, is that a pharmaceutical company?
A. Apologies for talking over you. I think they are a Japanese pharmaceutical company.
Q. And then lastly, Toxys, what is the business of Toxys?
A. Contract research organization. I would compare them with Gentronix, Litron. A new contract research organization that

comes up with novel assays that they've patented, so that kind of work. Contract research organization and inventors and sellers of their products.

Q. Now, do each of these industries that we've gone through elect to be affiliated with the genetic toxicology committee?

A. My understanding is, is that's correct, but they will not be a part of all of the different subgroups.

Q. Do they have representatives that serve on the genetic toxicology committee?

A. They do, but not all of them on the quantitative group to which this work is focused.

Q. Which of these companies have committee members on the quantitative subcommittee group?

A. The most precise way for this answer would be the list of coauthors on my publication in May 2021 titled Permitted Daily Exposure -- Daily Exposure Limits for

Noteworthy N-nitrosamines. There's a list there. Would you like me to read those?

Q. Are all of the coauthors on the Permitted Daily Exposure Limits for Noteworthy N-nitrosamines on the quantitative subcommittee with you?

A. Yes, they were active members on this publication, which is a part of the quantitative subgroup's output.

Q. Okay. Was there -- were there any members on the quantitative subcommittee that were not coauthors of the Permitted Daily Exposure Limits for Noteworthy Nitrosamines article?

A. There would be. As I was mentioning, there's an active group and then there's a group of people who are keeping updated.

So this would be the active group, and then there would be the people with interest in the topic as a larger body of that group. So those would not be coauthors on these. There's people that have an interest but have no active role in this

work.

Q. Are all of the individuals that have an active role in this work coauthors?

A. Yes, that's my understanding of that, yes.

Q. So who are those individuals that serve on the quantitative subcommittee group with you?

A. We have the people on my paper. Myself and Andreas chair the group, and Paul White is an active member. He was cochair, but due to workload, has now stepped back. But he's in a leadership position with myself and Andreas Zeller.

And then depending on the project, people will come in or not to be an active participant in the next publication. For example, the next one is being created by Health Canada to carry out risk assessments using confidence intervals for -- from BMD for mutation and cancer, and that will be directed -- I think the next two papers are Health Canada-focused projects that will have an expanded list of authors who will

contribute to that manuscript.

So it's a bit fluid depending on which subproject, due to level of expertise. These are very expert papers and not everyone can contribute to a suitable level.

Q. The ones that are coming out that you mentioned were going to be Health Canada-focused projects, are they going to be dealing with nitrosamines?

A. They will not deal with nitrosamines. A big area of interest for that group is PAHs.

Q. Okay. Could you tell me the names of the quantitative subcommittee members that you serve with? I think you said you were going to reference your research article.

A. Yes. The members relevant to today's discussion are entirely this subgroup that actively worked on this nitrosamine paper, and those are the names that I will read now.

Shall I -- so Krista Dobo,

Page 74

Bhaskar Gollapudi, Jim Harvey, Julia Kenny, Michelle Kenyon, Anthony Lynch, Sheroy Minocherhomji, John Nicolette, Veronique Thybaud, Ryan Wheeldon, Andreas Zeller. That's the complete list.

Q. And Krista Dobo, she works for Pfizer, correct?

A. Yes, unless she's changed roles recently, that would be correct.

Q. At the time that the work on the article was underway, she worked for Pfizer?

A. Yes. And to expand on that question, each of these numbered affiliations were correct and remain correct at this time.

Q. Meaning the numbers -- the affiliations that are noted on the research article itself?

A. Correct.

Q. So Bhaskar Gollapudi?

A. Bhaskar Gollapudi.

Q. Was affiliated with Exponent?

A. Correct.

Q. A consultant?

Page 75

A. Correct.

Q. Jim Harvey was affiliated with GlaxoSmithKline, correct?

A. That is correct.

Q. Julia Kenny, also affiliated with GlaxoSmithKline?

A. That is correct.

Q. Michelle Kenyon, affiliated with Pfizer, as was Krista Dobo, correct?

A. That is correct.

Q. Anthony Lynch, also affiliated with GlaxoSmithKline?

A. That is correct.

Q. Sheroy Minocherhomji, am I pronouncing that correctly?

A. You're pronouncing it as well as I can.

Q. Okay. Affiliated with Amgen?

A. According to -- I don't work with him on a regular basis, but this is correct information here, Amgen.

Q. John Nicolette, affiliated with AbbVie, correct?

A. Yeah, correct.

Page 76

Q. Veronique Thybaud, affiliated with Sanofi, correct?

A. Yes, that is correct.

Q. Okay. Ryan Wheeldon, or Wheeldon or Wheeldon, he actually worked some with you at the university?

A. That's correct.

Q. Does he work in your department?

A. He is finishing up his Ph.D. project with me.

Q. And then Andreas Zeller works for Hoffman-La Roche, correct?

A. That is correct. And the significance of him being last author is, as I've mentioned previously, he cochairs this group with me and has a very active role in understanding this topic too.

Q. Now, you mentioned Paul White had taken -- had an active role in this Genetic Toxicology Committee at the time that this research article was being worked on, correct?

A. He did, yes. He focused on

Page 77

other projects -- I think maybe three other publications -- and therefore did not have time to work on this project with us.

Q. Did he work on this project with you at all?

A. He would have seen our publications and discussed our work with us with his expert understanding. So to that extent, providing critique and so on.

Q. And when you say would have seen our publications, meaning he would have had input into the drafting of this article, would have reviewed it before it was published?

A. Not into the drafting, but the output figures were presented to the Genetic Toxicology Technical Committee, and at that time, he would have discussed his opinions of the topic at that time.

Q. And when you say output figures, what are you referring to?

A. The dose-response modeling within that publication. He's an expert on BMD and will have had some opinions on that.

Page 78

We wrote a paper together on adjustment factors, and he had a good opinion on that. Those main points.
Q. So his area of expertise is dose-response modeling?
A. Yes.
Q. And I see here it's -- did you say BMD or BND?
A. BMD, for which I'll mention later, so I'll expand now, means benchmark dose. So BMD, benchmark dose.
Q. But he is not a coauthor on the paper, correct?
A. That is correct.
Q. Did you ask him to be a coauthor on the paper?
A. We discussed it, but workload issues, he didn't contribute to the publication.
Q. And where does Mr. White work?
A. He works in Ottawa at Health Canada and has a professorship at the university there as well, at University of Ottawa, I think.

Page 79

MS. LOCKARD: We've been going about an hour and a half, so when you get to a good stopping point, can we take a break?
MS. BOGDAN: Sure, we can take a five-minute break right now if you'd like.
MS. LOCKARD: Sure.
THE VIDEOGRAPHER: Going off the record. The time is 10:35 a.m.
(Recess taken, 10:35 a.m. to 10:49 a.m. BST)
THE VIDEOGRAPHER: Back on the record. The time is 10:49.
BY MS. BOGDAN:
Q. Could we pull up the exhibits for the 2018 2nd Impurities seminar?
(Whereupon, Deposition Exhibit Johnson-4, 2nd Impurities: Genotoxic and Beyond Summit Slide, was marked for identification.)
MS. LOCKARD: The 2018.
THE WITNESS: Will this appear as Exhibit 4 or should I look at Zoom?

Page 80

MS. LOCKARD: It should come up on both.
THE WITNESS: Okay.
MS. BOGDAN: If we could please mark that as the next exhibit.
MS. LOCKARD: Exhibit 4.
THE WITNESS: I can see it on Zoom, and I don't need to scroll, so I'm happy. I can see it.
BY MS. BOGDAN:
Q. Is this the seminar or summit that you were previously testifying about that took place in Berlin in June of 2018?
A. As far as I'm aware, it is, but I'm scanning for Informa, and cannot see Informa on that slide.
Q. Okay. And that exhibit indicates -- excuse me -- that it took place on June 7th and 8th?
A. That exhibit does indicate that, correct.
Q. And it took place at the Mövenpick Hotel in Berlin. Is that where the seminar took place?

Page 81

A. That's what it says on the exhibit, correct.
Q. Okay. Is that where you remember the seminar taking place in Berlin?
A. I remember it taking place in Berlin. I can't recall the exact name of the hotel.
Q. Okay.
MS. BOGDAN: If we could please pull up the next exhibit and mark it Exhibit 5, which would be the presenters at the 2nd Impurity genotoxic and beyond summit.
(Whereupon, Deposition Exhibit Johnson-5, Speakers at 2018 Berlin Summit, was marked for identification.)
BY MS. BOGDAN:
Q. And please let me know once that appears for you on the screen.
A. I can see this on Zoom, so it's appearing on the screen, correct.
(Telephonic interruption.)
THE WITNESS: We have a phone

Page 82

call.
MS. LOCKARD: False alarm.
BY MS. BOGDAN:
Q. Would you please look at that exhibit and tell me if those appear to be -- well, first, let's see.
Are you on that exhibit?
A. Yes, I'm on that exhibit.
Q. Okay. And do those appear to be the individuals that spoke at that 2018 summit in Berlin?
A. That appears to be correct, and triggered my memory that I didn't attend all of the lectures.
Q. So you attended part of the seminar?
A. Correct.
Q. Which lectures, if you can remember, did you attend?
A. I'm fairly confident I attended Andrew Teasdale's lecture. The rest, I potentially did not see. Definitely Andrew Teasdale.
Q. Okay. Andrew Teasdale spoke

Page 83

about what?
A. From my recollection, Andrew Teasdale spoke about how the chemistry, about how NDMA could be produced as an impurity in these drugs. That's what I recall.
Q. Meaning the actual chemical reaction, like...
A. Exactly, the chemical reaction for producing this in this instance.
Q. And this exhibit indicates that he worked for AstraZeneca at the time?
A. Correct, and he was a leading expert in genotoxic impurities at the time as well.
Q. Okay. And then did you meet Dr. Russ Naven at that conference?
A. I'm looking closely for the face, because I do not know that person.
I do not think so.
Q. How about Mike Urquhart, do you know that individual?
A. I'm unsure at this conference whether I've met him. I've met him at a conference on impurities.

Page 84

Q. So you know him as you sit here today, but you're not sure if you met him there?
A. "Know him" is too strong. I'm aware of him and have been on these conferences at the same time as him.
Q. And he works for GSK to your knowledge?
A. To my knowledge, that's correct.
Q. And Dr. Raphael Nudelman who is depicted there is the gentleman we've already spoken about who works for Teva, correct?
A. That is correct.
Q. How about Dr. Alexander Amberg with Sanofi, do you know that individual?
A. I do not know that individual.
Q. What about Lance Smallshaw with UCB Biopharma, do you know him?
A. I do not know Lance Smallshaw.
Q. How about Dr. Lutz Müller with Hoffman-La Roche?
A. I do know him and have met him previous to this session. We worked together

Page 85

on the comparable case on EMS.
Q. When you say the comparable case of EMS, what does EMS stand for?
A. EMS stands for ethyl methanesulfonate.
Q. And why did you refer to that as a comparable case?
A. I refer to it as a comparable case because it's a ethylating agent that causes DNA adducts and DNA mutations in a very comparable way to these nitrosamines, and within their impurity issue in Viracept, they calculated a PDE that was accepted based on the understanding that low levels of this alkylating agent were repaired by DNA repair and the PDE calculation could be produced and accepted. So it's very comparable in my opinion.
MS. BOGDAN: Just off the record for a second.
(Discussion off the stenographic record.)
BY MS. BOGDAN:
Q. What is EMS?

Page 86

A. I answered that in the previous statement. EMS is ethyl methanesulfonate, an alkylating agent.
Q. I should have asked the question better. I'm -- is it a component -- is it a drug itself? Is it a pharmaceutical?
A. It's a genotoxic impurity that was found in a batch of Viracept, an impurity.
Q. Okay. And Viracept would be the pharmaceutical?
A. That was the affected pharmaceutical to which a certain batch had levels of EMS as an impurity.
Q. And EMS is not a nitrosamine, correct?
A. It's definitely not a nitrosamine, but it is an alkylating agent with a very similar mutagenic and adduct profile to these substances.
Q. Is it in the class of N-nitroso compounds?
A. It is not.
Q. What is an N-nitroso compound?

Page 87

A. An N-nitroso compound covers all of the compounds with nitro aspects to them.
Q. And can you describe what you mean by a nitro aspect to them?
A. I'm not a chemist, but there's a group of these nitroso compounds to which there are a hundred that contributes to TTC, so chemically I would not like to expand on what they are.
(Clarification requested by the stenographer.)
A. TTC, threshold for toxicological concern calculation.
BY MS. BOGDAN:
Q. And so because you're not a chemist, you would defer to the chemists to describe N-nitroso compounds as far as their chemical composition and makeup?
A. I would defer to chemists for that aspect. My focus would be on their interaction with DNA, that repair, and the link to carcinogenicity.
Q. Are nitrosamines a group of

Page 88

chemicals that are encompassed in the larger group of N-nitroso compounds?
A. Yes, that is correct, as far as I'm aware.
Q. Can you describe the characteristics of a nitrosamine?
MS. LOCKARD: Objection, form, vague.
A. As stated, I'm not a chemist, and I would not like to describe the chemical nature of this group of nitroso compounds.
BY MS. BOGDAN:
Q. Do you generally know what makes an N-nitroso -- or strike that.
Do you generally know what makes a chemical an N-nitroso compound?
A. It would be the nitrogen group and the oxygen group.
MS. LOCKARD: Did you say would be the nitrogen group?
A. It would be descriptions around the nitro -- nitrogen group and the oxygen group.
BY MS. BOGDAN:

Page 89

Q. And aside from describing N-nitroso compounds as having a nitrogen group and an oxygen group, can you elaborate any further with regard to the chemical structure of N-nitroso compounds?
MS. LOCKARD: Objection, vague.
A. As stated, I would not describe the chemical nature as I'm not a chemist.
BY MS. BOGDAN:
Q. Did you actually publish an article with Dr. Müller?
A. I would have to look back over my publication record to confirm or deny that. I -- as I sit here today, I'm not aware whether I have or have not.
Q. Did you produce any type of writing, whether it be peer reviewed and published or not, with regard to the EMS matter that you worked with Dr. Müller on?
MS. LOCKARD: Objection, vague as to "produce."
A. The EMS publications within my publication record, the mechanistic studies on EMS were linked to Hoffman-La Roche.

Page 90

BY MS. BOGDAN:
Q. When you say were linked to Hoffman-La Roche, meaning they were the authors?
A. They were the industrial sponsors for the postdoctoral research that carried out the work and that grant paid for the researcher and for the consumables for that project to produce those related papers.
Q. And did you work personally on those?
A. I did not work personally on the wet work, the lab bench work, but I worked on the analysis of the data, the production of the study design and so on, and the drafting of the report within my publication list on this topic.
Q. And was that work done at the university?
A. At the university, correct.
(Clarification requested by the stenographer.)
A. Yes, that work was carried out at the university by my postdoc and myself.

Page 91

BY MS. BOGDAN:
Q. And what time period are we speaking of that the work was done?
A. I would have to see my publication record for the exact dates. I think it's the Zair publication.
Q. Is that in your CV, Dr. Johnson?
A. I'm looking at my CV now. It's in my -- it's in my CV, Zair, et al. Z-A-I-R, et al., 2011, N-Methylpurine DNA Glycosylase Plays a Pivotal Role in the Threshold Response of Ethyl Methanesulfonate-Induced Chromosome Damage, in Toxicological Sciences.
Q. Back to the exhibit that still should be up on your screen, there's a Dr. Wichard who works for Bayer.
Do you see -- we're on the second column, second person down.
A. I see him, and I'm looking at the others. I do not know that person.
Q. How about Dr. Vanderkelen who worked for Nelson Labs? Do you know her?

Page 92

A. I do not know her.
Q. How about Dr. Qiu who works for Boehringer Ingelheim?
MS. LOCKARD: Objection, vague.
BY MS. BOGDAN:
Q. Do you know Dr. Qiu?
A. I do not.
Q. Do you know Dr. Tom Van -- it's -- I don't know how to pronounce the last name, W-I-J-K, who's with Abbott Healthcare?
A. I do not know him and have not talked to him, but I have seen his work in presentations, so I know of him.
Q. How about Dr. Catrin Hasselgren with Genentech, do you know her?
A. As far as I'm aware, I do not know her either.
Q. Okay. And with Intertek, Dr. Tino Otte, do you know him?
A. As far as I'm aware, I do not know him.
Q. Looking at this list of speakers, other than attending Dr. Teasdale's

Page 93

presentation, does looking at this list of speakers refresh your recollection of any other presentations you attended?
A. It reflects my recollection that I did not attend those other ones, and I focused on Andy Teasdale. I was aware he was an expert and went to his talk. I cannot recollect any others due to being chemistry focused and not in my area of interest or expertise.
Q. What do you consider yourself an expert in?
A. I consider myself an expert and I have been told by many people globally to be an expert in genetic toxicology. Of course I've been told I'm an expert in benchmark dose-response modeling. I've also been told by regulators that I have a high level of expertise in human health risk assessment as well.
Q. The first area that you mentioned was genetic toxicology. Could you define genetic toxicology?
A. Genetic toxicology is an area

Page 94

of toxicology focused on compounds producing genetic damage to DNA. To test for this, you have a battery of mandated tests with OECD guidelines, and for this particular topic, a modification of that guideline within the ICH guidance.

So it's a mandated series of tests to test to see if genetic damage has occurred from these compounds, the mechanism of how it's occurred, and more advanced, of what levels it does not occur, and so on.

So mandated part of industrial and regulatory testing of compounds to see if they're mutagenic or not, and potency and mechanism and so on.

Q. Now, the second area that you mentioned was benchmark dose-response modeling. Would you please describe what that is?

A. Benchmark dose statistical modeling is applying a series of statistical models to toxicology and cancer bioassay data to derive a benchmark dose, and that benchmark dose is defined as a point of

Page 95

departure for those animal tests, and that's wrapped up in itself.

And then the next area that you'll ask me about will be risk assessment. So that part is defining a point of departure with advanced statistical modeling from in vivo, relevant robust test systems. That's what benchmark dose modeling is.

Q. What is cancer bioassay data?

A. In order to carry out a risk assessment for cancer, the cancer bioassay must be adhered to. There's guidelines on this topic from the OECD, where it's specified routes of administration, tissues that should be assessed, study design, animal husbandry and so on.

So there's a mandated way to carry out cancer bioassay analysis in rodents. This is in my list of references as well. And from that, you get the best data that adheres to this test guideline, and you can do a hazard assessment on it if you're a hazard-based organization. We can do a risk assessment if we're talking about risks on

Page 96

those data.

Q. Bringing it down to a little bit more simple, what is actually a cancer bioassay study, like what physically is it?

A. Physically, get a group of rodents, treat them with a compound for the lifetime of those rodents, sacrifice the animals, carry out pathological assessment to see levels of tumors and positions of tumors all through the organs of those individuals.

Q. And when you say treat them with a compound, is -- what is the purpose of treating them with a compound?

A. It's different depending on what the compound is and what it's predicted to be, et cetera. If we want to see if a substance is carcinogenic to animals, then we carry out this test to see is something carcinogenic in animals or not.

Then the more advanced version of the assay, in an expanded one with multiple doses, multiple numbers of animals, you can carry out dose-response analysis and actually define a level on that dose response

Page 97

that you can extrapolate away from the animal concentration to human.

And that's where we get to the risk assessment, because we can use those concentrations in that way.

Q. And is that the type of methodology that was used in the Peto study of NDMA and NDEA?

A. Yes. And that was one of the most robust cancer bioassay studies that I've actually ever seen. It's a really extensive dataset that was fantastic for my benchmark dose analysis and statistical modeling.

Q. And is it the most extensive dataset that you have seen with regard to NDMA and NDEA?

A. It is. For that endpoint of cancer in animals, it definitely is.

Q. And the endpoint for that study was actually cancer, correct?

MS. LOCKARD: Objection, form, vague.

BY MS. BOGDAN:

Q. What was the endpoint of that

Page 98

study?
A. The endpoint was cancer in the animals tested.
Q. And did the study run for -- how long?
A. As far as I'm aware, from reading it, it abided to the OECD guidelines and was a lifetime exposure or the animals were sacrificed at two years.
Q. And for a study that has cancer as the endpoint, is it desirable to have a lifetime exposure study?
A. For the study itself, there's advantages to it. For the risk assessment where we're discussing lifetime exposure, then you would need to do that from a lifetime exposure study. So within that, you have the option.
So it's a good test system for us to make these assumptions in human health risk assessment from.
Q. Where did you gain your experience with regard to risk assessment?
A. I've been doing consultancy

Page 99

with companies on this specific topic for numerous years, and in those, we submit -- I submit risk assessments based on this type of modeling, calculating PDEs and so on, and submitting those as risk assessments to the regulatory bodies.
I've also got experience with the regulatory bodies in doing risk assessments. I've worked with the RIVM, the National Institute of Health on a couple of cases -- not cases, a couple of example compounds where we did the dose-response modeling and calculate levels of risk with different risk assessment procedures.
And I was provided with lots of this expertise by a close working relationship with numerous regulators within the HESI GTTC and also specifically on this topic with Wout Slob, the leading expert on risk assessment based on the benchmark dose approach. I've been developing that expertise for numerous years.
Q. Now, are you referring to HESI, that working with regulators within HESI, or

Page 100

were you talking about another group?
A. I was referring to HESI, Health Environmental Science Institute, and the regulators, regulatory experts within that.
Q. And how long have you been affiliated with the HESI group?
A. The exact definition, the exact year, I do not know. But I've worked for numerous years and predict it would be 2010.

Page 102

1

Page 104

1

21

Page 103

1

14

Page 105

1

16

Page 106

[redacted]

BY MS. BOGDAN:

Q. You mentioned that you had worked with doing risk assessments with regulatory bodies, and I think you testified that you had submitted risk assessments to regulatory bodies.

Can you please tell me what risk assessments you submitted to regulatory bodies?

A. I've done numerous of these. These are documented and carried out in a consultancy role under Swansea Innovations in my university, abiding to the roles of

Page 107

consultancy.

When we carried out the -- when I carried out these risk assessments, I've been doing numerous of these. One I did the Cobalt Consortium on Cancer and carried out the analysis, submitted it to the RIVM at that time, and then to ECHA, the European Chemicals Agency.

I carried on working on that issue, and due to my working relationship with RIVM, did some further work on Cobalt with RIVM as well through -- with Wout Slob as well.

The related ones to -- more related to today's case, I've worked on different industries, focused mostly on this topic. If there's a genetic toxicant that I can -- we understand the mechanism or we can show that low levels are withstood, then we carry out an in vivo dose-response analysis to find the point of departure, and then carry out the risk assessment.

So those are what I'm talking about, and the ones related to today would be

Page 108

with the pharmaceutical companies, where I've carried out those calculations on parent drugs. So the whole drug, and then added a safety factor to get to a level of human intake that's okay for the clinical trials. Calculated those, submitted them for a risk assessment. Those have been accepted.

I've done similar ones for genotoxic impurities within other pharmaceutical products, carried out these analyses, submitted them to the regulatory bodies, and those have been accepted as well.

And that's my answer.

Q. You used the term "RIVM"? What does that stand for?

A. I cannot say the exact term because it's a Dutch -- there's some Dutch words in there. RIVM, it's the Dutch National Institute of Health, but those are the correct letters.

Q. And that's the project you did with the Cobalt Consortium on Cancer?

A. Yes.

Q. Who funded that research?

Page 109

A. It started with the Cobalt Consortium, so the companies who produced cobalt and had industrial exposure to cobalt.

Q. So they were the manufacturers of cobalt that --

A. As far as I --

Q. -- that work?

(Clarification requested by the stenographer.)

BY MS. BOGDAN:

Q. So it was the manufacturers of cobalt that funded that work?

A. As far as I'm aware, and that was through the Cobalt Consortium.

Q. And what was the purpose of that study?

A. It was a hazard, not risk-based, assessment. It was a hazard-based assessment to see the potency of cobalt as a carcinogen in these -- in the cancer bioassay, so it was a hazard-based potency assessment.

Q. And was the assessment with regard to coming into contact with cobalt by

Page 110

breathing it, by ingesting it, by -- through the skin or something else?
A. I cannot remember the route of administration for the animal studies which I assessed, but they were relevant at that time.
Q. Do you know what exposure or the type of exposure that the Cobalt Consortium on Cancer was concerned about?
A. I do not know the -- I do not know that at the current time. I did at the time, but now I do not know that.
Q. Were they concerned about cobalt coming from a medical device?
A. My understanding -- it may be incorrect -- was battery production in industry. The workers producing products with cobalt, that was the concern.
Q. And this type of risk assessment work that you did, was that provided to the Cobalt Consortium on Cancer?
MS. LOCKARD: Objection, form, misstates the testimony.
///

Page 111

BY MS. BOGDAN:
Q. You did a risk assessment for the Cobalt Consortium on Cancer, correct?
A. It was a hazard-based assessment, not a risk assessment. They're slightly different.
Q. Right. Okay, I'm sorry, I misspoke. I forgot you had made the distinction.
So the hazard risk assessment that you did for the Cobalt Consortium on Cancer, was that submitted to any regulatory authority?
MS. LOCKARD: Objection, form, misstates the testimony.
A. As my understanding, created the report. That was submitted to the regulators, the RIVM in that regard. And I worked with the RIVM. They were -- had an active interest in my work. It was quite advanced. And yes, they did submit to the regulators.
BY MS. BOGDAN:
Q. And when you say you worked

Page 112

with the regulators, did the RIVM hire you as a consultant or did you interact with them as a representative of the Cobalt Consortium on Cancer?
A. The RIVM did not recruit me as a consultant, so I would have been on behalf of the Cobalt Consortium.
Q. Now, you also mentioned that you had done risk assessments for pharmaceuticals. Am I remembering that correctly?
A. Yes, correct.
Q. Who hired you to do risk assessments on behalf of -- or of pharmaceuticals?
A. I could not recall all of the companies, numerous companies, where I did these assessments on their substances, including GSK, Dart, and I would have to recall to a list which resides with Swansea Innovations to expand on that list. But none of those were nitrosamines.
Q. And so you would do these risk assessments at the request of the

Page 113

pharmaceutical company and then provide the risk assessment back to the pharmaceutical company, correct?
A. Yes, that would be correct. I would prepare the risk assessment in a similar way to this, submit that to the pharmaceutical company, correct.
Q. And it would be the pharmaceutical company that would actually present the risk assessment to the regulators, correct?
MS. LOCKARD: Objection, form, speculation.
A. The regulatory submissions would include my documents in their submission.
BY MS. BOGDAN:
Q. And you said they -- your work did not involve nitrosamines, your previous work?
A. What -- as far as I'm aware, that is correct. That work did not include nitrosamines.
Q. Did it involve contaminants in

Page 114

pharmaceuticals?
A. In some cases, they were impurity assessments, correct.
Q. And how do you define an impurity?
A. I would refer back to the impurity guidance within the ICH, including degradants, and there's a list within the ICH of what an impurity is defined as.
Q. As you sit here today, how would you define an impurity?
A. I would define impurity as a substance that's within a pharmaceutical -- a genotoxic impurity in pharmaceuticals as a substance that could be a degradant or a byproduct within the process of making the finished article.
Q. Now, when you say a substance, that would be a chemical?
A. That would be a chemical. That's how I would define "substance" in that statement.
Q. And would it be a chemical that was not intended to be in the drug product?

Page 115

A. As an impurity, within this area of producing chemicals, there's an understanding that a hundred percent purity is not achievable, and this is why the ICH impurity regulation exists to instead talk about presence or absence, we talk about concentrations and levels of impurities that are acknowledged to be present in such substances and such drugs.
Q. And would your risk assessments address the appropriate, in your opinion, levels that should be allowed in the drug products?
A. They have done. They would be calculations to ensure that a human exposed to that level of that substance had no increased risk of whatever endpoint that was, so if it was mutation, mutation; if it was chromosome loss, then chromosome damage; if it's cancer, then cancer, in that regard.
Q. And would your work be confined to the area of genotoxic risk assessment?
A. It would not. That's my initial area of expertise, and as I

Page 116

demonstrated with, for example, the work of the Cobalt Consortium, I have that experience with cancer bioassay data as well. In some of my publications, you'll see -- such as when I work with the RIVM assessing cancer bioassay data and benchmark dose confidence intervals. I have upcoming projects on that with Health Canada as well. Then those would be covering cancers in addition to genetic toxicology.
Q. So you look at chemicals that are carcinogens that are not necessarily genotoxic?
A. My particular area of expertise is genotoxic carcinogens. I do not work with nongenotoxic carcinogens that act via different mechanisms to induce the cancer.
My area of expertise would be mutagenic carcinogens where it's well characterized, and it could be through other genetic damage processes leading to the cancer.
Q. What is your Ph.D. in? What field?

Page 117

A. Ph.D., it was within the department of biology, now medicine. The title of the Ph.D. is Mechanistic Investigations of the Quantitative and Qualitative Effects of Genotoxicants. So I developed other understanding throughout that learning process, but my Ph.D. is in genetics and in genetic toxicology, and as you see from the title, in mechanisms underlying those, which include DNA repair, and also the quantitative aspects, including dose-response modeling, and qualitative, yes or no, effects of genotoxicants. So an expanded version of my Ph.D. title would include those different aspects.
Q. But that is different than risk assessment, is it not?
A. It is different to risk assessment. It's the initial step in risk assessment is defining points of departure that can then be used in risk assessment.
So I initiated this expertise calculating those points of departure that could then be used for risk assessment. I

Page 118

started my training on that data defining those and then got to the stage of applying that throughout my career.

Q. So risk assessment was not part of your bachelor's degree and your Ph.D., correct?

MS. LOCKARD: Objection, compound.

BY MS. BOGDAN:

Q. Risk assessment training was not part of your bachelor's degree studies, correct?

A. Aspects of risk assessment training were included in my Ph.D. My Ph.D. was linked to the European Union PEPFAC funding, which was to --

Q. I --

A. Pardon?

MS. LOCKARD: Can he finish?

BY MS. BOGDAN:

Q. I'm sorry, sir. I had asked about your bachelor degree studies, not your Ph.D. studies.

A. Oh, apologies. I heard you say

Page 119

both.

Q. So I'll read back my last question.

Risk assessment training was not part of your bachelor's degree studies, correct?

A. In my bachelor's degree, I carried out two modules on genetic toxicology and information around hazard and risk assessment in that module as taught by Professor Jim Parry at that time.

I did an undergraduate project on genetic toxicology, which was linked to risk assessment through the analysis of bisphenol A. You'll see my first publication in 2002 was on bisphenol A, was on mechanisms, was on dose response. That linked to a European Union risk assessment project on aneugens, and also the European Food Safety Authority -- the U.K. version of that, the Food Standards Agency, were also involved and party to that big paper.

So I would say through those modules and through my dissertation, I was

Page 120

trained -- I was -- my training on risk assessment was initiated.

Q. Did the work that you personally did involve mechanisms and dose response?

A. In this undergraduate project on bisphenol A, mechanisms and dose response, and then expanded application of that information in the rest of the report.

Q. Did you actually perform the risk assessment yourself or was that -- you said linked to a risk assessment project. Was the risk assessment project performed by others?

A. That would be correct at that time, and I was aware of those being -- those taking place.

Q. And your Ph.D. is in genetic toxicology through the department of biology?

A. I -- my Ph.D. was within genetic toxicology, and within that, I expanded on my undergraduate project again on bisphenol A, and I think on -- on bisphenol A and on alkylating agents and their mechanisms

Page 121

of action and their dose response. And I was learning and understood the application of that to hazard and risk assessment, and that was at the Ph.D. stage.

Q. Did you actually do a hazard or risk assessment as part of your Ph.D. thesis?

A. That was not included as part of the output within my Ph.D. thesis, but I attended numerous conferences where this was discussed and included, and also my supervisor was carrying these out and linked to groups such as the committee on mutagenicity where these were being carried out.

So not entirely within this, but through my training it was started at that time, my understanding and training around hazard and risk assessment.

Q. Do you consider yourself a regulatory expert?

A. I've been considered by others, including regulators, as a regulatory expert, so to quote them, I would state that I'm considered as an expert in regulatory

practice.

With this particular focus on what we're talking about today, with dose response, when we're talking about PDE with acceptable intakes, with margins of exposure, yes, I am considered an expert in those particular applications within risk assessment.

Q. And when you say you're considered an expert by others, who are those others?

A. In verbal conversations -- and we can come back to names when we get that piece completed -- but the straightforward one would be I was on the expert panel for the European Medicines Agency on this topic, and I was a stated expert on that group.

Q. And when did this take place and what group was this? Did you say the EMA?

A. EMA, European Medicines Agency. I have a date somewhere.

Q. Are you looking at your CV to try to --

A. I am looking at my CV to try to find a date. Okay.

On my CV at the bottom of the Awards, Achievements, Positions of Responsibility, invited expert to EMA 2020 nitrosamine expert consultation, with the number afterwards, for the record, EMA/80573/2020.

But to be invited to an expert group by a regulatory body assumes that they consider you as an expert.

Q. And where are you referring to on your CV, Doctor, just so that I make sure I'm in the same place.

A. Hopefully it's the first page. Mine says page 1, and I think it is page 1. There's my name, there's my address --

Q. Oh, at the bottom of the --

A. Awards, Achievements -- Awards, Achievements and Positions of Responsibility. It's the bottom bullet point in that section.

Q. Okay. Who else was invited as an expert to that EMA 2020 nitrosamine consultation?

A. The scientists that I remember and I know of -- I'm sure those -- that information is public for you to expand on my answer -- would be Bernd Kaina, Professor Bernd Kaina of Mainz University, who is the global expert on MGMT and DNA repair.

There were other experts, I can't remember their names. There was an epidemiology expert. There was an expert that had been involved in the cigarette smoke instance, and there was -- I think there was ten in total, and apologies for not remembering the names.

Oh, apologies, one more. Jan van Benthem from the RIVM. Jan van Benthem.

Q. And when you said you considered yourself a regulatory expert, is that limited to points of departure, benchmark dose, dose response within the field of genetic toxicology?

A. I'd expand that statement to include based on cancer bioassay data as well.

Q. Do you consider yourself an

expert in epidemiology?

A. I do not consider myself an expert in epidemiology.

Q. Directing you to the Amended List of Materials Considered -- now, have we marked that as an exhibit or is that part of the -- your report that's already been marked?

A. Can you clarify the question?

Q. I'm not sitting there with you in the room, so I can't see if the report -- your report that's been marked already as an exhibit has Exhibit A attached to it and Exhibit B, or if it's standing alone, so to speak.

(Conference out of the hearing of the stenographer.)

MS. LOCKARD: They were served together. It was served as an exhibit with the report, but Exhibit 2 is just the report.

MS. BOGDAN: Okay.

MS. LOCKARD: So he's got the amended list in his hand if we want to

mark it as Exhibit 6.
MS. BOGDAN: So could we pull up, then, the amended Exhibit A and B of his report, and then mark that separately, if it was not included with the report itself?
THE STENOGRAPHER: Just to clarify, A and B together will be Exhibit 6?
TRIAL TECHNICIAN: Exhibit A and B are part of the report. Exhibit A starts on page 70, Exhibit B starts on page 79.
MS. BOGDAN: That's perfect. I just --
TRIAL TECHNICIAN: Which page would you like to see, Exhibit A, which is his CV?
MS. BOGDAN: No, I would like to go to, I guess what you said was page 79, which would be the start of the Amended List of Materials Considered.
TRIAL TECHNICIAN: Okay.

MS. LOCKARD: I -- the version we have here doesn't have page numbers on it for the record, but he does have the amended list in front of him.
MS. BOGDAN: I think it's just the page number of the PDF. It doesn't have a -- and we can refer to it at this point with the page number that's right on the bottom of the List of the Materials Considered.
BY MS. BOGDAN:
Q. So do you recognize this document, sir?
A. I recognize the document that's being presented on Zoom, correct.
Q. Now, this document is 25 pages long, I believe?
A. I believe that too.
Q. And how many documents are listed on the Amended List of Materials Considered? Do you know?
A. I have not counted them in this format, no.
Q. Would you agree with me that

there's hundreds?
A. I prefer not to make guesses, but it looks like a large number, towards that amount.
Q. Now, are these materials that are listed here materials that you were provided by counsel?
A. So on page 1 would be the materials passed on by GT. If that's another name for counsel, then that would be that.
Q. So the MDL -- let me just -- so the record is clear, I'm sorry, I didn't mean to speak over you. There's just a little delay.
The -- so under Materials Considered, the MDL pleadings and general documents were materials you got from counsel, correct?
A. Correct.
Q. The expert reports --
A. Yeah, again, from --
Q. -- would be materials you got from counsel?
A. I would agree with that. Thank

you for highlighting them.
Q. The next section, which is entitled Deposition Transcripts With Exhibits, are those materials that you received from counsel?
A. Yes. As far as I'm aware, yes, definitely.
Q. And they continue on to page 2 as well. Again, materials from counsel?
A. These were provided by counsel.
Q. Okay. Now we get to a section called Regulatory Guidances and Documents.
Do you see that?
A. I do see that.
Q. Were these provided by counsel?
A. Many of these were -- these -- so a lot of this is from my own research and from preparing for presentations and preparing my report. I would have got a lot of these independently.
I think where we see in the second column like a Teva mark on it, you may interpret this as being passed on by counsel, but the ICH M7 guidance is obviously

Page 130

something that I would have looked at and that I have to reference as well.

So these documents are ones that I researched and digested, considered and went into my report, independently of counsel, as far as I'm aware.

Q. Okay. If we could go to page 3, please. And there's a document that is about two-thirds of the way down the page, it starts with 2019 ICH Q3D(R1).

Do you see that?

A. I do see that.

Q. That was added in the Amended List of Materials Considered. Why was that added?

A. To ensure that there was a latest revision of the ICH Q3D guidance which relates to this, because there's an expanded version of the PDE calculation within that.

Q. And that was not previously listed on your materials considered, correct?

A. Correct. That was a typo.

Q. Even though the date of your report was August of 2020, correct?

Page 131

A. The date of my report was August 2020.

Q. So at the time that your report was issued, that 2019 guidance was in existence, correct?

A. Yeah, that's correct.

Q. Now let's go to the next section on page 5, which is Literature and Standards.

A. I can see on your screen and I have this in front of me.

Q. Okay. Where did those materials considered originate from? Were they provided by counsel or through your research?

A. These would be through my research and included in developing my understanding of this topic from contribution to this work and to just developing my understanding of the topic, so from myself.

Q. If we could go to the next page, please. I see a lot of references in this materials considered list to TEVA-MDL.

Do you see that over on the

Page 132

right-hand column?

A. I see that, yes.

Q. Who were you originally hired by as an expert in this case?

A. By GT.

Q. On behalf of what defendant?

A. On behalf of Teva, as far as I'm aware.

Q. Are you serving as an expert on behalf of defendants other than Teva?

A. Yes, I am.

Q. When did that change?

A. That changed at the beginning of this year, when my role changed from a consultant, where I was developing an understanding of this topic, to the preparation of my report. At that time I was made aware by counsel that I was working for a wider group of affected companies.

Q. Did they tell you who those companies were?

A. They did, yes.

Q. And who are those companies?

A. Well, my pronunciation and

Page 133

recollection may not be precise, include Mylan, ZHP, Prinston and one beginning with A with "bindo" at the end, I think. There may be more. That's my recollection. So more than Teva.

Q. Aurobindo?

A. Yeah, that sounds correct.

Q. How about Hetero?

A. Hetero, yes, I think I'm representing them as well. Yes, they're included.

Q. As we go on in this materials considered list, especially once we get to page 19, which has Company Documents Produced --

A. I'm going to look at your screen for this bit.

Q. -- all of those documents appear to be Teva documents; is that correct? Teva/Mylan?

A. That's what it states here.

Q. Did you read all these documents?

A. I had access to and considered

Page 134

these documents.
Q. And when you say I had access to and considered them, what does that mean as far as your activity with regard to these documents?
A. If the document was relevant to my risk assessment, then I read it. If not, I would be aware of it and had access to it.
Q. So that means you opened each and every one of these documents that are listed under Company Documents Produced to make that determination?
A. If the title was in the name and it didn't look relevant, then maybe not. But yes, I would have opened all the ones that were relevant and considered whether to bring in information from other ones as well.
Q. And if we go on to page 20, all the documents on that page are also Teva documents, correct, as far as how they're identified?
A. As far as how they're identified, they are Teva documents on this page.

Page 135

Q. And moving to page 21, they're all identified as Teva documents, correct?
A. According to this page, they are identified on the right column as Teva documents, and then you can see from some of the statements, HHA for valsartan produced -- products provided by Mylan, et cetera. So the other companies do appear here as well.
Q. Do you have any understanding of any relationship between Teva and Mylan?
A. I am aware that some of the companies made the API and then the generic companies included those APIs in the products; and the exact relationship, I will not comment on now.
Q. If we look at page 22, they're also all Teva documents, identified as such?
A. Yeah, according to the right column there, they're stated as Teva documents.
Q. And then on page 23, we have some Teva documents, and then there are a few documents with Auro or APL, which the description indicates are Aurobindo

Page 136

documents, correct?
A. I can see that that's correct from what you've just said on this document.
Q. And then moving on to page 24, again, we have some Aurobindo documents, some Mylan documents and some Teva documents, with one document towards the very, very bottom, second up from the bottom, that says ZHP Response to DMF Information Request Letter, Prinston.
Do you see that?
A. I do see that.
Q. Did you ask for more company documents to be produced from ZHP at the time that you were asked to serve as an expert for all defendants?
A. I cannot recall requesting that information.
Q. Is this materials considered list comprehensive of all of the materials that you considered in forming your opinions in this matter?
A. It is. From my understanding, this is very comprehensive.

Page 137

Q. So if a document is not on this list, you did not consider it?
A. I've been working on this topic for my whole career and read many documents that formed my expertise in this area, and those would lead to my ability to make these risk assessment judgments.
So in that regard, this is comprehensive of my decision, and I would support that these were comprehensive and linked to my report entirely, but I wanted to make that statement as well, that I've always worked on this topic and I've read many documents in this area as well.
Q. With regard to internal company documents that would have been produced by the defendants in the litigation, if the document is not on this list of materials considered, is it fair to assume that you did not consider it?
A. From my understanding, that would be correct.
Q. Do you know of the journal Environmental and Molecular Mutagenesis?

Page 138

A. I do know of that journal, yes.
Q. And how do you know of that journal?
A. I know of that journal, it's a very good journal in this area of genetic toxicology. It's linked to the American Environmental and Genomic Society. It's very highly linked at the current time to Health Canada, which have been senior editors on it previous to -- they still contain many Health Canada experts, and within my area of genetic toxicology, it's a preferred journal for many experts, including the regulatory experts, where we see it as a top journal in genetic toxicology.
Q. Who is the editor-in-chief of Environmental and Molecular Mutagenesis?
A. I think it's -- at the current time it's Bhaskar Gollapudi. And I think previous to that was -- apologies. Bhaskar Gollapudi at the current time, and for our paper which we published this year, the editor was Carol York -- Carol Yauk, Y-A-U-K, who handled the publication because Bhaskar

Page 139

was a coauthor on the publication. So she was editor for this latest EMM publication on PDE. Apologies for the long answer.
Q. So Bhaskar Gollapudi is the editor-in-chief of Environmental and Molecular Mutagenesis even currently, correct?
A. I think that is correct, but the leadership changes frequently, so I think it's correct to the best of my knowledge.
Q. But for the purposes of the publication entitled Permitted Daily Exposure Limits For Noteworthy N-nitrosamines, Carol -- did you say Yauk?
A. I think that's a suitable way of pronouncing it.
Q. -- served that role of editor because he was a named author in the article, correct?
A. Correct, yes. And I think that's standard practice in publishing as well.
Q. When were you first retained as a consultant to do work on this matter?

Page 140

A. I think we opened discussions with GT and Teva at the beginning of 2019, and that relates to my first invoice in 2019.
Q. Do you have a copy of that first invoice that you had in 2019 with you?
A. It is currently not in front of me.
MS. BOGDAN: Does counsel have a copy of that? The first invoice that we have in the production is in 2020.
MS. LOCKARD: I have hard copies. Are you using one as an exhibit?
MS. BOGDAN: I would like to use all of the invoices as exhibits, and I don't believe the 2019 invoice was in the production.
THE WITNESS: I'm --
MS. LOCKARD: Hold on, there's no question.
The invoices were all in the production.
MS. BOGDAN: We have pulled

Page 141

them out, and the first one starts in 2020.
MS. LOCKARD: Yeah, he -- he may have misspoke. You can ask him about it, but we have all the invoices.
BY MS. BOGDAN:
Q. Dr. Johnson, did you do work in 2019 on this project for Teva?
A. I became -- we signed the documents in 2019, and I misspoke. It was 2020 for the invoice, I think. But you see from my recollection of the dates, we need to go by the invoice.
Q. Did you do work for a period of time before you billed?
A. I have it in front of me. The date I misspoke on. I said 2019. The date is actually the 11th of the 9th, 2020, the sum of 30,000 --
MS. LOCKARD: No. Just listen to the question. Just hold on. You're racing through.
THE WITNESS: Apologies.

Page 142

MS. BOGDAN: Why don't we pull up the exhibit that's entitled Invoices, and we can mark these.

(Whereupon, Deposition Exhibit Johnson-6, Invoices, JOHNSON000037 - JOHNSON000044, was marked for identification.)

THE STENOGRAPHER: That's Exhibit 6.

MS. LOCKARD: Okay. And is this a collection of all four?

MS. BOGDAN: I believe so, that they were put into one exhibit.

Is that an eight-page exhibit, because there's fronts and backs, of all four invoices? I could ask our tech.

TRIAL TECHNICIAN: Eight pages total in this file.

MS. BOGDAN: Right, okay. So there's fronts and backs of each, so...

TRIAL TECHNICIAN: Looks like a total of four invoices, yes.

Page 143

MS. BOGDAN: Okay. So yes, they're all together. So this is Exhibit 6.

BY MS. BOGDAN:

Q. Doctor, I'd ask you if you can please take a look at the first page of Exhibit 6, and tell me if you recognize that document.

A. I do recognize that document.

Q. And what do you recognize that document to be?

A. I recognize this document to be my first invoice to GT on this topic.

Q. Did you have any invoices that you submitted to Teva for your work on this project?

A. No, not that I'm aware of, no.

Q. Okay. And does this first invoice encompass all your work up until the date of the invoice?

A. That is -- that would be correct.

Q. And that would be 91 hours of time?

Page 144

A. That's -- that sounds correct, at my rate. Yes, that sounds correct.

Q. When did you begin your work? That 91 hours of work, when did it start?

A. I cannot give an exact date because I do not know that answer.

Q. Can you give an approximate number of months you've been working on this project before submitting your invoice in November of 2020?

MS. LOCKARD: Objection, form.

A. I could not --

MS. LOCKARD: Vague.

A. I would not want to approximate that, but I can confirm I did count -- I did carry out this amount of hours.

BY MS. BOGDAN:

Q. Did you keep a record of the number of hours you worked by day to then come up with the 91-hour total that's reflected in the invoice that's been marked as Exhibit 6?

A. At the time I would have done, and I don't need that document anymore, and

Page 145

don't have that, that time. I've got that for the current time and the time I have yet to invoice for.

Q. Did you do work on this project in the year 2019?

MS. LOCKARD: Objection, form, vague as to "project."

A. I do not know the answer to that.

BY MS. BOGDAN:

Q. Who first contacted you about serving as a consultant for Teva?

A. Raphael Nudelman, and we linked with GT.

Q. Do you have any record as to when Raphael Nudelman contacted you?

A. I do not have that record personally.

Q. How did he contact you?

A. I would predict by e-mail.

Q. Did you save that e-mail?

A. I do not know.

Q. What did Ralph say in that e-mail?

Page 146

A. I do not know. The assumption would be to initiate consultancy with GT.
MS. LOCKARD: Don't speculate, please. If you remember, you can answer, but you don't have to assume or speculate.
THE WITNESS: Okay.
BY MS. BOGDAN:
Q. Generally, what did Ralph communicate to you in that e-mail? Not the exact words he used, but generally, what was the e-mail about?
A. I think it was to explain my work to Teva.
Q. And when you say explain my work, what do you mean by that?
A. My presentations on this topic at that time, explain that work to Teva, yeah.
Q. Meaning explain the type of work you do?
A. Explain the slide set presentation that I had delivered to Impurities conferences to Teva.

Page 147

Q. Is that like the Impurities conference that took place in June of 2018?
A. Exactly that.
Q. Did you present that information at more seminars than the June of 2018 one that took place in Germany?
A. I did present the evolving level of work at other Impurities conferences.
Q. And when did those take place?
A. I do not know exact dates. Frequently over the last couple of years.
Q. Do you know where they took place?
A. Before the travel ban, in Berlin; Mainz, Germany. And then travel ban -- post travel ban, via online conferences.
Q. So there are two in-person that you remember?
A. In Berlin and Mainz, Germany that I remember.
Q. And how many online conferences have you done?

Page 148

A. I have done -- I do not know the number and will not approximate.
Q. Has there been more than one?
A. There has been more than one.
Q. Has there been more than 10?
A. I do not know.
Q. And these invoices are in pounds?
A. These invoices are in Great British pounds.
Q. And who generates these invoices?
A. Swansea Innovations generates these invoices.
Q. Is Swansea Innovations separate from Swansea University?
A. There's a good statement in here to answer this question. Swansea Innovations is a wholly owned subsidiary of Swansea University.
Q. And you're referring to right on the invoice itself where you're reading that?
A. Correct. On your screen too.

Page 149

Q. Are you an employee of Swansea Innovations?
A. I'm an employee of Swansea University and carry out consultancy through Swansea Innovations.
Q. And when employees of Swansea University do consultant-type work, is that done through this wholly owned subsidiary?
A. Yes, it is.
Q. And as such, Swansea Innovations bills for your time?
A. That would be correct.
Q. And then how are you compensated for your work doing consultant services like you've done in this case for Teva?
A. Swansea Innovations takes 20% of this value. My college, Swansea University Medical School, takes 5% of this value. The remaining funds go into that month's paycheck through PAYE to account for tax, et cetera.
Q. And what does Swansea Innovations use with the percentage that it

Page 150

retains?
A. I do not know. I should not assume.
Q. Does all your consultant-type work go through Swansea Innovations?
A. Yes.
Q. What percentage of your income per year is derived from doing consultant work?
A. I have not made that calculation.
Q. Can you provide an estimate?
A. My wage is 60,000.
(Clarification requested by the stenographer.)
MS. LOCKARD: Yeah, I just want to object if we're asking him about his salary, but I --
MS. BOGDAN: Yeah, I didn't ask him about his salary. I was asking about the percentage of his income that he derives from doing consulting work.
MS. LOCKARD: Yeah, if you can

Page 151

do the math in your head --
THE WITNESS: Apologies.
MS. LOCKARD: It's fine. But a percentage, not amounts.
A. It is -- I have my wage, which is a value. My consultancy is half of that value on top of that value.
BY MS. BOGDAN:
Q. So an additional 50%?
A. That's a better statement -- (audio malfunction) --
(Clarification requested by the stenographer.)
A. That's a better statement. That's an additional 50%, is the average for my consultancy work.
BY MS. BOGDAN:
Q. If we could go to the next invoice that's dated April 20th, 2021, and that's for an additional 35 hours of work?
A. Okay. Yeah, I agree, 35 hours of work additional. Yes, agree.
Q. Okay. And then the next -- I think we have the wrong exhibit up. Okay.

Page 152

Then the next invoice in that same exhibit, which is dated -- is it dated July 5th, 2021 or May 7th, 2021?
A. This is the English format, and it's July 5th.
Q. Thought so. Okay.
And that's for an additional 35 hours of work?
A. Yeah, I agree with this, yes.
Q. Okay. And then the last invoice is July 28, 2021, and that's for an additional 70 hours of work, correct?
A. Yeah, I agree that's correct.
Q. Did you keep any type of record of what actual work you did, meaning something that's itemized as to what you spent your hours doing?
A. No, I did not.
Q. So other than these invoices, there's no written record of how you spent that time?
A. Correct, no written record of how I spent the time.
Q. Do these invoices include all

Page 153

the time that you spent up until the time that you generated your written report?
A. Yes, they include that time within these invoices.
Q. If we could please pull up an e-mail, which is Teva document 443142.
(Whereupon, Deposition Exhibit Johnson-7, E-mail(s) re: Limit of NDEA in Sartans, TEVA-MDL2875-00443142, was marked for identification.)
THE STENOGRAPHER: This will be Exhibit 7.
MS. BOGDAN: Mark it Exhibit 7.
BY MS. BOGDAN:
Q. Doctor, Exhibit 7 should now be hopefully up on your screen. Can you see that?
A. I can see it in very small text. Is this available in the other format? Excellent.
MS. LOCKARD: I'm sorry for the interruption, but I can't get anything past Exhibit 5 on my document box. Is it just me?

Page 154

(Technical comments off the stenographic record.)
MS. BOGDAN: Did that work?
MS. LOCKARD: I have it now. Do you have it, Dr. Johnson?
THE WITNESS: I have that now, thank you.
BY MS. BOGDAN:
Q. This is an e-mail from Ralph Nudelman dated November 14th, 2018, to an individual by the name of Claire Lyons.
Do you know Claire Lyons?
A. It does not ring a bell. I do not think I know Claire Lyons.
Q. And Corey Sawyer is copied on it. Do you know Corey Sawyer?
A. As far as I understand, I do not know Corey Sawyer.
Q. And in this e-mail, if I could direct your attention to the first paragraph, which reads: Claire, from so many e-mails on this topic, I lost track of what we had previously discussed, and I would like to go back to an e-mail I wrote on September 20th,

Page 155

copy attached, where I calculated a limit for NDEA based on BMDL10 and not on linear extrapolation from the TD50.
Then, open parens: There were several follow-up e-mails to that one with further clarifications, close parentheses, period.
Do you see that sentence?
A. I do see that sentence.
Q. Did you provide to Ralph Nudelman a calculation limit for NDEA based upon BMDL10 --
A. Not that -- I'll let you --
Q. -- prior to November 14th, 2018?
A. This was linked to my presentation at the former meeting where I presented a BMDL10 analysis on these compounds, and this will relate to that presentation and slide set. Nothing more.
Q. Did Raphael Nudelman attend your presentation?
A. Yes, I think that he did.
Q. And as part of your

Page 156

presentation, you presented on that exact issue?
A. I'm confident that I did.
Q. And you presented on a benchmark dose limit as opposed to linear extrapolation from a TD50?
A. I'm confident that I did, yes.
Q. And did you provide any type of written materials to the attendees of that seminar?
A. Not that I recall.
Q. Was it presented by way of a PowerPoint?
A. It was presented by way of a PowerPoint.
Q. Were the attendees given copies of the PowerPoints that were used by the presenters?
A. I do not know.
Q. As a speaker, did you have to provide a copy of your PowerPoint to the seminar organizers?
A. I do not know. Conferences act in that regard in different ways.

Page 157

Q. Do you still have that particular slide where you presented a BMDL10 limit for NDEA?
A. I have multiple slides with that statement in addition to my publication on that topic.
Q. And has the calculation basically been the same since 2018 for the BMDL10 for NDEA?
A. The full publication, I would reanalyze the data to ensure the precision, so because there's prepublished data, there is room for that number to change.
Q. Do you know what that number was in 2018 when you presented at the seminar that Raphael Nudelman went to?
A. No, I do not.
Q. Would you be able to search your records to see if you still had a copy of that PowerPoint that was presented in 2018?
A. My way of working is I get the slide date and update it for the next conference, so I wouldn't be confident in

finding that.
Q. You mentioned earlier in your testimony the name of the company that organized this conference. What was the name of that company?
A. Informa is what I think the company is called, I-N-F-O-R-M-A, I think.
Q. And do you know where they're headquartered?
A. I do not.
Q. Are they in Europe or do you just not have any idea?
A. I do not know.
Q. How were you contacted to present at that seminar?
A. I do not know.
Q. Did someone recommend you to be a speaker at that seminar?
A. I do not know.
Q. Were you told what topic they wanted you to speak about at that seminar?
A. I do not know.
Q. Do you know how they got your name as a potential speaker?

A. No, I do not know.
Q. Had you ever spoken at an Informa seminar before?
A. I had not.
Q. Had you ever attended an Informa seminar before?
A. I had not.
Q. Did Informa pay for your travel to the seminar and your hotel?
A. Yes, I think so.
Q. Was this the first time that you spoke publicly regarding nitrosamine impurities in pharmaceuticals?
A. Yes, I do think so.
Q. Did Informa provide you any information upon which to base your presentation on?
A. No, I do not think so.
Q. Now, referring you to the next sentence in the e-mail, which reads: The rationale to use BMDL10 instead of TD50 is [as read] I very nicely explained in the Valsartan Art 31 uAR 19.9.18, open parens, to MAHs, close parens, document, copy attached.

Are you aware of the existence of that document?
A. That does not ring a bell. I do not know that title for that document.
Q. Then the next sentence reads: I believe this was written by George Johnson of Swansea University, who is the super expert of this field, and thus, I had recommended him as an external expert.
Do you see that?
A. I do see that.
Q. Do you know of a document that explained the rationale to use BMDL10 instead of TD50 that was written by you that would have been in existence as of November 14th, 2018?
A. I do not know beyond the PowerPoint presentation from that Informa meeting.
Q. Now, that meeting was in June of 2018, correct? And this e-mail is dated November of 2018.
Did you have any contact with Ralph Nudelman between the June of 2018

conference and the date of this e-mail?
A. I don't think so.
Q. As of the date of this e-mail, had you been contacted by Teva or GT to serve as an external expert for Teva?
A. I can't recall.
Q. Do you see the next paragraph in this e-mail that begins with "The BMDL10"?
A. I see that.
Q. Would you please read that paragraph?
A. The BMDL10 represents an estimate of the lowest dose which is 95% certain to cause no more than 10 -- than a 10% cancer incidence in rodents, as the point of departure for the calculation of excess cancer risk.
Q. Is that a sentence that was written by you? Do you recognize that sentence?
A. That's a sentence that could relate to many documents on the BMDL calculation.
Q. Do you agree with that

Page 162

sentence?
A. I do agree with that sentence.
Q. Does it look familiar to you?
A. Looks familiar in the fact that it's in most publications on this topic, a very similar statement to that.
Q. Have you written a statement similar to that?
A. Within my publications you will see statements very similar to that.
Q. And then with regard to the second sentence, which reads: The BMDL10 is considered to represent a more realistic point of departure for risk estimations in low-exposure scenarios more realistic point of departure for risk estimations in low-exposure scenarios than the TD50 value.
Does that sentence look familiar to you?
A. With the same regard, that looks similar to any publication along these lines.
Q. Could those two sentences have come off your PowerPoints from the 2018

Page 163

seminar that you did in Berlin?
MS. LOCKARD: Objection, form, speculation.
A. I do not know, and I don't want to speculate.
MS. BOGDAN: If we could please pull up the next exhibit, which is Teva document that ends in 492386.
(Whereupon, Deposition Exhibit Johnson-8, E-mail(s) re: Snodin & Elder Commentary, TEVA-MDL2875-00492386, was marked for identification.)
THE STENOGRAPHER: That's Exhibit 8.
BY MS. BOGDAN:
Q. And please let me know once you're able to visualize that.
A. I'm able to visualize that on Golkow.
Q. Okay. And that's an e-mail from Ralph Nudelman to you, correct?
A. That's correct.
Q. And what is the date of that

Page 164

e-mail?
A. This is American format, but I think it's the 26th of the 3rd, 2019.
Q. So it would be March 26th, 2019?
A. Looks that way.
Q. Do you remember getting an e-mail from Ralph Nudelman in March of 2019?
A. I don't remember specifically, but many experts send me on publications that they deem relevant.
Q. At the time that you got this e-mail from Ralph Nudelman, were you doing consulting work for Teva with regard to the nitrosamine contamination of valsartan products?
A. I cannot recall.
Q. Well, did you have any e-mail exchanges typically with Ralph Nudelman before you were hired as an external consultant for the company?
A. Not that I can recall.
Q. So your e-mail communications with him began after you were hired to work

Page 165

as an external consultant for Teva, correct?
MS. LOCKARD: Objection, form.
A. I have e-mails from many experts, and they send me information, but I would not have had information around details of this, of the consultancy, prior to starting up the official consultancy.
BY MS. BOGDAN:
Q. So it's your testimony that this e-mail would have been after you had been approached and agreed to serve as a consultant for Teva?
MS. LOCKARD: Objection, form, misstates the testimony.
A. I don't know. It could have come after. It could have come before. I do not know.
BY MS. BOGDAN:
Q. Did you have Ralph Nudelman's e-mail address before you were hired as a consultant for Teva?
A. I don't think so. I'd never worked with him previously.
Q. Was there any type of agreement

Page 166

between yourself and Teva regarding working as an expert for them?
MS. LOCKARD: Object to form, vague.
A. I do not know that information.
BY MS. BOGDAN:
Q. Was there any type of a retainer agreement or writing between you or Swansea Innovations and Teva that set forth the nature of the type of work you were going to do and how much you were going to charge to do it?
MS. LOCKARD: Objection, form, ambiguous.
A. I don't think so.
BY MS. BOGDAN:
Q. How would we determine the date on which you started to do consulting work for Teva?
MS. LOCKARD: Objection, form, ambiguous.
A. I do not know the start date.
BY MS. BOGDAN:
Q. Do you have any record, whether

Page 167

it be on a calendar or otherwise, that would indicate when you started doing consulting work for Teva?
A. I do not have that information, no.
Q. Would Swansa -- or Swansea, excuse me, Innovations, have any such written record as to when you began doing consulting work for Teva?
MS. LOCKARD: Objection, form, ambiguous.
A. I do not know.
BY MS. BOGDAN:
Q. Do you notify Swansea Innovations if you have been approached and have agreed to do consulting work?
A. I do, and they generate these invoices.
Q. Well, that's after you've done the work, correct?
A. Yes.
Q. What about initially when you're agreed to do the work, do you do any type of notification to Swansea Innovations

Page 168

to let that subsidiary of the university know that you are going to be doing consulting work for a particular company?
A. Yes, and they will -- yes.
Q. How do you go about notifying them?
A. I will e-mail Swansea Innovations with that information.
Q. Do you have a copy of the e-mail that you sent to Swansea Innovations with the information that you had been approached by Teva to do consulting work?
MS. LOCKARD: Objection, form, ambiguous.
A. I do not have that e-mail.
BY MS. BOGDAN:
Q. Would Swansea keep a copy of that e-mail?
A. I do not know.
Q. What is the purpose of sending Swansea Innovations that e-mail?
A. To initiate the consultancy documentation.
Q. And what is the consultancy

Page 169

documentation particularly?
A. Conflict of interest -- nondisclosure agreements, often, are those forms. Mostly those -- mostly nondisclosure agreements, if they're required by the company.
Q. Was there a nondisclosure agreement required by Mylan -- by Teva?
A. Not that I'm aware of at this time for this first invoice.
Q. Now, this first invoice is for 91 hours of time. How many hours a week did you work on this project approximately, back in the fall of 2020?
A. I do not know. It wasn't a strict number of hours per week.
Q. The 91 hours of work that's billed for on the November 9th, 2020 e-mail, what months of 2020 was that work done in?
A. I do not know.
Q. Was some of it done in October of 2020?
A. That would be an assumption, but could be correct.

Page 170

MS. LOCKARD: When we get to a stopping point, let's take a break, because I know we've been going for an hour and a half or so.

BY MS. BOGDAN:

Q. Well, would the 91 hours of work have been done in November of 2020 in total, like all of it done in November of 2020?

A. No, that did not happen.

Q. So we know some of the work occurred before November of 2020; is that fair?

A. That is fair.

Q. Did you do any work consulting for Teva during the summer of 2020?

MS. LOCKARD: Objection, form, ambiguous.

A. I would have been reading the regulatory documents related to this issue and to my consultancy with GT and Teva during months previous to October.

BY MS. BOGDAN:

Q. Can you give me an estimation

Page 171

of the number of months previous to October of 2020 that you would have been doing work reading regulatory documents in connection with your consultant work for Teva?

MS. LOCKARD: Objection, form, ambiguous.

A. I couldn't give you an accurate assumption, no.

MS. LOCKARD: So I'd like to take a break now. So, Rosemarie, what would you like to do about a lunch break? Because we have food here that's been sitting.

MS. BOGDAN: Oh, I wasn't aware because I'm obviously not there. If -- there's just one more document on this topic that I wanted to show, so I'm happy to take a break, but it makes sense to just do this one more, and then take a lunch break. It's just a one-page document.

MS. LOCKARD: Okay. If there's just a couple of questions.

MS. BOGDAN: Okay. It's

Page 172

really -- it's just a one-page document, and you'll see it when I put it up. It's Teva 425960.

(Whereupon, Deposition Exhibit Johnson-9, E-mail(s) re: Snodin & Elder Commentary, TEVA-MDL2875-00425960, was marked for identification.)

THE STENOGRAPHER: And that's Exhibit 9.

BY MS. BOGDAN:

Q. And, Doctor, when you can see that, please let me know.

A. Okay. Not yet. Still not there.

Q. It's only one page, so it shouldn't take too long.

A. But it's not here.

I've got it.

Q. Okay. Do you see that? It's an e-mail?

A. I see that.

Q. And what is it dated?

A. 26th of the 3rd, 2019.

Page 173

Q. Okay. And is that e-mail from you?

A. That is my e-mail address, g.johnson@swansea.ac.uk.

Q. And who is the e-mail to?

A. To Raphael Nudelman with cc'd in other people, Brian McCormick and Rachel Gallagher.

Q. And are they all, to your knowledge, affiliated with Teva Pharmaceuticals?

A. Yes, as far as my knowledge from their e-mail addresses, they look associated with Teva.

Q. And do you remember sending this e-mail?

A. I do not remember sending this e-mail, but if someone sends me a document, the subject for this is Snodin & Elder, it's polite to reply.

Q. At the time that you replied to this e-mail, were you doing work for Teva as a consultant?

MS. LOCKARD: Objection, form,

Page 174

ambiguous.
A. I do not know. I do not think so.
BY MS. BOGDAN:
Q. And why don't you think so?
A. The nature of this e-mail was passing on a commentary on this topic.
Q. What about the nature of the e-mail passing on commentary on this topic makes you think you weren't doing consulting work yet?
A. Because the previous e-mail that this was replied to that you showed me previously was a one-sentence passing me on this commentary with no further information, which you could assume would be given if consultancy and detailed analysis of the situation would have started.
Q. Meaning the shortness of the redacted portion? Is that what you're referring to?
A. Of the previous e-mail that looks like related to this one. This is Snodin & Elder commentary. The previous

Page 175

exhibit you showed me was what this is replying to, as far as I'm aware.
Q. Did you keep copies of your e-mails back and forth with Raphael Nudelman?
MS. LOCKARD: Objection, form.
(Clarification requested by the stenographer.)
A. I do not think so.
MS. BOGDAN: All right. Did you want to take a break, Victoria, for lunch?
MS. LOCKARD: Yes. It's 1:20 in the afternoon here, so let's do that.
THE VIDEOGRAPHER: Going off the record. The time is 1:20 p.m.
(Recess taken, 1:20 p.m. to 2:03 p.m. BST)
THE VIDEOGRAPHER: Back on the record. The time is 2:03 p.m.
BY MS. BOGDAN:
Q. Good afternoon. Can you hear me?
A. Good afternoon.

Page 176

Q. Okay. Good.
Now, I have previously asked you about being familiar with the journal Environmental and Molecular Mutagenesis before we took the break.
A. Yes, you had previously asked me about that.
Q. That's right. And you have actually published several articles in that journal, correct?
A. That is correct.
Q. How did you first come to publish in that journal?
A. Potentially as a coauthor on a publication with another coauthor, and then realizing it was a suitable journal. Potentially as a coauthor.
Q. Do you know the first journal that you published as a coauthor in Environmental and Molecular Mutagenesis?
A. I do not.
MS. BOGDAN: Why don't we please bring up exhibit C2, which should be entitled Mutation as a

Page 177

Toxicological Endpoint for Regulatory Decision-Making.
(Whereupon, Deposition Exhibit Johnson-10, Mutation as a Toxicological Endpoint for Regulatory Decision-Making, by Heflich et al, was marked for identification.)
THE WITNESS: I don't have it yet. Oh. Here.
A. I have that on my desktop now.
BY MS. BOGDAN:
Q. Okay. We don't seem to have it up on our screen. I don't know if the other people on Zoom can see it, but I don't. There we go. I think that's the first time it's hit your screen before our screen.
A. Yay.
TRIAL TECHNICIAN: Double click.
BY MS. BOGDAN:
Q. All right. Now, with regard to when you're a coauthor on a publication, do you have a choice as to which journal the publication is submitted to for publication

or is that the primary author's call usually, in your practice?

A. It can go any way. There can be any decision made. There's no standard process for deciding on a journal article, a journal to target.

Q. For example, with this particular journal article that's been marked as Exhibit 10, was there a discussion between the coauthors as to where it would be submitted for publication?

A. I cannot remember. I see a big link with these coauthors in that journal.

Q. Okay. And when you say you see a big link with these coauthors in that journal, what makes you say that?

A. Bob Heflich, Robert Heflich from FDA, used to be an editor on it. Bhaskar Gollapudi is an editor on it, the current editor. Paul White was a lead editor as well, and Francesco Marchetti, both of those from Health Canada. I'm unsure with Kristine Witt, whether she's been involved on the editorial board. So that's why I make

that statement.

Q. And was Bhaskar Gollapudi the editor-in-chief at the time that this particular article was published back in 2019?

A. I do not know, either him or Francesco Marchetti.

Q. How did you first meet Bhaskar Gollapudi?

A. I met him at the HESI Genetic Toxicology Technical Committee. That's where I met him.

Q. And did he serve on that committee with you?

A. He did at that time, yes.

Q. And what time period are we talking about?

A. Towards generation of our publication in 2013, so the lead-up to generate that publication.

Q. So that didn't come out as clearly with the connection.

So sometime working up to the 2013 publication?

A. Correct.

Q. Is that what you --

A. Correct, yes.

Q. Okay. What 2013 publication are you referring to?

A. I'm going to look at my CV for the exact. Yep.

Found it. There's plenty of coauthors, Gollapudi, et al.; we include numerous FDA and Health Canada, all those authors. So many authors on that. Gollapudi, et al. 2013, Environmental Molecular Mutagenesis and so on.

So I'll read the title. Quantitative Approaches for Assessing Dose-Response Relationships in Genetic Toxicology Studies.

Q. And is that the first study that you coauthored with Gollapudi?

A. I think it is, yes.

Q. And what company does Gollapudi work with or for, if you know?

A. At the current time?

Q. In -- well, is there a

difference between now and back in 2013?

Who did he work for in 2013, if you know?

A. One of two, Exponent or Dow, Dow Chemical. Either Exponent or Dow Chemical.

Q. He worked for Dow Chemical before he worked for Exponent?

A. Yes, he did, and may have had a job in between. Those are the two major jobs that I'm aware that he's undertaken, the companies that he's worked with.

Q. And currently does he work with Exponent?

A. Yes, I think he does.

Q. And the title of this commentary is Mutation As a Toxicological Endpoint for Regulatory Decision-Making, correct?

A. Yes, I see that's correct.

Q. Okay. And you are the second noted author on this publication, correct?

A. That is correct.

Q. Did you note on this

Page 182

publication that was published in October of 2019 any conflicts of interest?
A. May I look at the statement? I'm not sure. I don't think conflicts of interest were stated, that there was any conflict of interest for this publication.
Q. At the time of this publication, you were working as a consultant for Teva in connection with this litigation; isn't that correct?
MS. LOCKARD: Objection, form, ambiguous.
A. My consultancy with Teva and GT, I did some of that in 2020, and we were preparing this manuscript for many years.
BY MS. BOGDAN:
Q. But at the time of its publication, you were doing consulting work for Teva, correct?
MS. LOCKARD: Objection, form, ambiguous.
A. I do not know. It says published online, 10th of October 2019. 2019? I do not know if that's the case.

Page 183

BY MS. BOGDAN:
Q. But you did not disclose any conflict of interest in this publication, correct?
A. Correct. This sort of publication would be more of a review concept-type document, and conflict of interest, from my interpretation, better linked to new opinions based on data.
MS. BOGDAN: If you could please pull up exhibit entitled Environmental and Molecular Mutagenesis, Author Guidelines, please.
(Whereupon, Deposition Exhibit Johnson-11, EMM Author Guidelines, Conflict of Interest Declaration, was marked for identification.)
THE STENOGRAPHER: That's Exhibit 11.
A. Okay. Yeah, I have those in front of me.
MS. BOGDAN: And have we marked this as an exhibit?

Page 184

THE STENOGRAPHER: Yes.
THE WITNESS: Is that question to me?
MS. BOGDAN: Exhibit 11?
THE STENOGRAPHER: Yes.
BY MS. BOGDAN:
Q. If I could direct your attention to the second page of the exhibit, under Conflict of Interest Declaration at the bottom of the page.
A. Okay. I can see that.
Q. Can you please read the first sentence of the Conflict of Interest Declaration?
A. At the time of submission, EMM policy requires that each and every author reveal any financial interests or connections, direct or indirect, or other situations that might raise the question of bias in the work reported or the conclusions, implications, or opinions stated.
Q. Does that sentence say anything about it being a review article versus original work?

Page 185

A. It does not state that, no.
Q. Please read the second sentence of the Conflict of Interest Declaration.
A. These include pertinent commercial or other sources of funding for the individual author or for the associated departments or organizations, personal relationships, or direct academic competition.
Q. Were you paid for your work consulting for Teva?
A. I'm paid by GT when consulting with Teva and GT.
Q. If we could go back to the first page of Exhibit 10, please.
A. I'm on that page.
Q. The decisions -- or excuse me, the opinions that you're giving in this matter, don't they deal with toxicological endpoints for regulatory decision-making?
A. The focus is on genetic toxicological endpoints, including mutation and including chromosomal data for that decision-making, and does not include making

Page 186

the decision based on cancer bioassay data.
Q. However, your report and your opinions that you've given in this case include evaluation of mutations for regulatory decision-making, do they not?
A. They include evaluation of mutations in order to define the mechanism, and this document does not define the mechanism. This document is around discussing -- using the metrics from the in vivo mutation data to define the point of departure for risk assessment, which is different.
Q. In this litigation, are you not proposing PEDs [sic] for NDMA and NDEA?
A. In this litigation, I'm proposing PDEs for NDEA and NDMA based on cancer bioassay dose response data, yes.
Q. But proposing PEDs, which are -- what does PED stand for, just so that the record is clear?
A. It's PDE. It's permitted daily exposure.
Q. And with regard to the opinions

Page 187

that you're offering for permitted daily exposures, that goes to regulatory concerns with regard to how much NDMA or NDEA can be in a pharmaceutical, does it not?
A. It does not, because the risk assessment I've carried out in my report is entirely around PDE metrics from the cancer bioassay data, and this commentary is to propose that in the future we could do that calculation on mutation data, but that's not what is done in my report, in my risk assessment here. So they are independent and different approaches.
Q. So you're actually distinguishing between mutation data and carcinogenesis data? Is that my understanding?
A. That is your understanding, with regard to using that data for a PDE calculation.
Q. Do you agree that your opinion involves regulatory decision-making and suggesting daily exposure limits?
A. That's not what this paper is

Page 188

about. My paper is about defining those from the cancer bioassay data and applying them to this instance.
Q. I'm not asking about the paper at this point.
Do you agree that your opinion in this case involves regulatory decision-making and suggesting daily exposure limits?
A. My opinion is based on defining a human exposure limit that can be applied in order to define whether a human is at increased risk of cancer.
Q. So this case involves defining human exposure limits, correct?
A. Correct, but from cancer data and not from mutation data, which is the entire premise of the commentary which we're discussing.
Q. Don't you cite to your 2021 Permitted Daily Exposure Limits for Noteworthy Nitrosamine paper as support for your decision -- or your opinions in this case?

Page 189

A. From my report submitted as my risk assessment for this, I did cite my PDE publication, and the decisions and opinions are based on the cancer-derived PDE metrics and not from the mutation-derived PDE metrics. They are very independent.
Q. So with regard to your opinions that you're offering in this case, you are not in any way relying on the mutation PDE values that you set forth in your 2021 publication entitled Permitted Daily Exposure Limits for Noteworthy Nitrosamines?
A. That's correct. My reliance here is on the cancer-derived PDE metrics where the mutations were presented in that publication for other reasons.
Q. And what were the other reasons that the mutations were presented in the 2021 publication but are not presented in your report in this litigation?
A. My area of research, including what we've discussed today, is -- and based on this paper, which you kindly put forward, the mutation toxicological endpoint for --

Page 190

(audio malfunction) --
(Clarification requested by the stenographer.)
A. -- for regulatory decision-making. So the mutation PDEs in my 2021 publication talk to this and say in the future, could we use mutation-derived PDEs, and if we did, what would they look like compared to cancer-derived PDEs.
Because in addition to these nitrosamines that we're looking at today, many nitrosamines do not have reliable cancer bioassay data. So if we could do the risk assessment on a more sensitive endpoint where we admit that we would have a lower PDE, would we still protect the human population.
So that's the premise of adding those mutation-derived ones in the conceptual format of that discussion in support of the decision, the ideas here.
But for the actual application to a risk assessment, we've got the cancer data. It's very strong cancer data, and we use that for our human health risk assessment

Page 191

and not the mutation data for the human health risk assessment in this instance.
BY MS. BOGDAN:
Q. However, in your 2021 research article, the one that we've been speaking about, Permitted Daily Exposure Limits for Noteworthy Nitrosamines, you did go about calculating PDEs for both NDMA and NDEA for cancer and mutation, correct?
A. That is correct, and we critique the mutation-derived PDEs and provide information about how future datasets could look and further concepts around adjustment factors in order to apply those in a future setting in a more conceptual way.
Q. And when you say in a future setting in a more conceptual way, meaning despite the fact you calculated these mutation PDEs in the article, you did it only for conceptual purposes?
MS. LOCKARD: Objection, form, misstates.
A. We did it in support of this idea that you could, in theory, use mutation

Page 192

data to derive PDEs. And in the paper, we present them in comparison to cancer-derived PDEs to see if they would still provide a concentration similar to the PDE or we predicted below the PDE because mutation occurs at a lower concentration in a cancer as supported by this. And we're working on future case studies along that line.
BY MS. BOGDAN:
Q. Okay. We will go back and talk more about the 2021 publication later.
With regard to the exhibit that is still, I believe, up on your screen --
A. Sorry. Okay.
Q. -- which is the Mutation as a Toxicological Endpoint for Regulatory Decision-Making?
A. It is no longer on my screen. Could you inform me which exhibit it is again, please?
Q. I believe it was exhibit -- was it 11?
THE STENOGRAPHER: 11 was the last one.

Page 193

TRIAL TECHNICIAN: It was Exhibit 10.
MS. BOGDAN: 10.
TRIAL TECHNICIAN: Yes.
A. I have it now.
BY MS. BOGDAN:
Q. Would this article pertain to Teva Pharmaceuticals, potentially in their work as a pharmaceutical company?
A. This article relates to that concept around using mutation data for risk assessment in future studies, so not linked to Teva. To the whole field of analysis, could we use mutation data in future risk assessments in the absence of cancer data.
Q. When you're talking about using mutation data, that could be used in the pharmaceutical industry, correct?
A. That could be correct, and it could also be applied to other industries and regulatory arenas too.
Q. If we could please bring up the next exhibit, which is an Environmental and Molecular Mutagenesis commentary entitled

Quantitative Interpretation of Genetic Toxicity Dose.

(Whereupon, Deposition Exhibit Johnson-12, Quantitative Interpretation of Genetic Toxicity Dose-Response Data for Risk Assessment and Regulatory Decision-Making: Current Status and Emerging Priorities, by White et al, was marked for identification.)

THE STENOGRAPHER: Chris, I'm showing that as 12?

TRIAL TECHNICIAN: That is correct.

BY MS. BOGDAN:

Q. If we could go to the first page of the commentary, please.

A. I think I have this. Is this the one downloaded from ResearchGate?

Q. Yes, I believe so, Doctor, and if you could go to the second page of the exhibit.

A. Yeah.

Q. Is this a commentary that you

coauthored?

A. Yes, it is a commentary that I coauthored with Health Canada experts.

Q. Does this commentary involve concepts such as point of departure metrics and benchmark doses?

A. It includes those concepts entirely related to genetic toxicology data.

Q. Did you disclose any conflicts of interest in this commentary?

A. I'm just searching to the conflict of interest part. Apologies.

I cannot see conflict of interest stated in this publication.

Q. If we could please go to the next exhibit, which is going to be a research article entitled Genotoxicity as the -- there we go -- Toxicologically Relevant Endpoint to Inform Risk Assessment.

(Whereupon, Deposition Exhibit Johnson-13, Genotoxicity as a toxicologically relevant endpoint to inform risk assessment: A case study with ethylene oxide, by Gollapudi

et al, was marked for identification.)

BY MS. BOGDAN:

Q. Is this another research article that you're a coauthor on?

A. This has yet to appear. Are we on Exhibit 13? Okay, I have it.

Q. Is the article up for you now, Doctor?

A. Yes, I have it now.

Q. Is this an article that you were a coauthor on?

A. Yes, it's an article I'm a coauthor on.

Q. Okay. And who are your coauthors on this article?

A. So Bhaskar Gollapudi, who we've talked about from Exponent. Abby Li from Exponent, Steave Su from Exponent, myself, Richard Reiss from Exponent and Richard Albertini, also called Dick Albertini, from Burlington, Vermont, University of Vermont College of Medicine.

Q. Now, when was this research article accepted? I believe it's at the top

of the --

A. Oh, excellent.

Q. -- page.

A. Accepted 4th of September 2020.

Q. And I see there are three dates on the top, received, and then revised and then accepted.

Could you describe that process for me, please?

A. With a publication in line with this one or any publication, you submit the publication, it gets reviewed by external reviewers, if you're lucky to get to that stage. Those external reviewers will critique the publication -- although at that stage, it's not a publication; it's a manuscript. Ask you -- they'll accept it, they'll give minor revisions, major revisions or reject.

Then you have a period where you can amend your publication in line with those reviewers' comments and editorial comments. That can be a long process, particularly in this example when it goes

over the summer, and then -- and then it's accepted and put on -- put online in the final publication.

Q. So the accepted date is the publication data, essentially, for online?

A. For online.

Q. So this particular research article was published September 4th of 2020?

A. Yes. The final accepted version was published then.

Q. Did you disclose any conflicts of interest in this publication?

A. In this publication, there was funding from the American Chemistry Council, and this was declared in the Conflict of Interest section.

Q. Did you personally declare any conflict of interest or disclose that you were doing consulting work for Teva Pharmaceuticals?

MS. LOCKARD: Objection, form, ambiguous.

A. In this statement, the conflict of interest covers the authors with the

American Chemistry Council. In my opinion, this does not work to the -- this was not relevant or applicable to the risk assessment report that I was compiling and generating for Teva and GT.

BY MS. BOGDAN:

Q. Even though the research article discusses points of departure and daily exposure values, correct?

A. With the same discussions that these were based on the genetic toxicology data.

Q. But this research article is dealing with points of departure, daily exposure values, using PROAST software and doing benchmark dose analyses; is that not true?

A. These analyses using PROAST and benchmark dose were on different datasets. They are called continuous datasets from genetic toxicology, carried out in a different way to when you do it on cancer bioassay data, which is contour datasets. So that calculation is different.

And the application of those datasets to create a PDE, as we've stated for cancer, is an accepted approach, and for genetic toxicology data, it's more a conceptual approach that's trying to gain momentum.

So I see quite a major -- distinguish a major difference between this and a risk assessment based on cancer bioassay data, as I've presented for GT and the clients.

Q. Does this research article discuss calculating daily exposure values, yes or no?

A. This article is used to calculate permitted daily exposure values from genetic toxicology data.

Q. And this article also discusses using a benchmark dose analysis, does it not?

A. This article also describes the use of the benchmark dose analysis on genetic toxicology data.

Q. And this article also discusses point of departure values, does it not?

A. This article also discusses the use of point of departure values from genetic toxicology data.

MS. BOGDAN: If you could please put up the next exhibit, which is a research article, The Use of Benchmark Dose Uncertainty Measurements.

(Whereupon, Deposition Exhibit Johnson-14, The use of benchmark dose uncertainty measurements for robust comparative potency analyses, by Wheeldon et al, was marked for identification.)

THE STENOGRAPHER: 14.

A. Okay. It's arrived. It's loading. I can see it.

BY MS. BOGDAN:

Q. Is this another research article that you coauthored?

A. This is another research article that I coauthored.

Q. And again, in the Environmental and Molecular Mutagenesis journal?

Page 202

A. Yes, that's correct.
Q. And this research article, again, refers to benchmark dose methods, correct?
A. This does refer to benchmark dose methods as the best statistical -- the best statistical approach for analyzing these sorts of data, yes.
Q. And it does benchmark dose modeling, correct?
A. This uses benchmark dose modeling on in vitro genetic toxicology data points, correct.
Q. And did you disclose a conflict of interest in this publication based upon the fact that you were doing consulting work for --
A. No, because it has even less relevance than the in vivo genetic toxicology BMDs that were generated. So these are in vitro BMD potency comparisons using the advanced statistical tool of benchmark dose.
Q. With regard to the conflict of interest declaration that we previously put

Page 203

up, with the EMM policy requiring that each and every author reveal any financial interest or connections, direct or indirect, or other situations that might raise the question of bias in the work reported, or the conclusions, implications or opinions stated, is it your testimony that research articles that you are doing that specifically address benchmark dose, which is the analysis that you're doing in this litigation, are not relevant?
A. If those benchmark dose analyses are on in vitro genetic toxicology data and in vivo genetic toxicology data, then they are not a conflict when I'm carrying out the risk assessment here on in vivo cancer bioassay data.
Q. So you were making a distinction between in vivo genetic toxicology data and cancer bioassay data in whether or not you need to disclose a conflict of interest?
A. I am making that distinction.
Q. Even though what you're

Page 204

calculating, benchmark dose, is -- or applies to both situations?
A. The calculation is completely different if we're talking about benchmark dose. As I've suggested, the cancer bioassay data is a quantum calculation using a different part of the BMD tool, using completely different statistical modeling from what you do on continuous data for genetic toxicity data, which uses a different suite of models. So they're very distinguished, yes.
Q. Aren't these articles favoring the benchmark dose method?
A. Which articles are we talking about?
Q. The article that's right up on the screen here, The Use of Benchmark Dose Uncertainty Measurements for Robust Comparative Potency Analyses.
A. This publication -- okay?
Q. I'm sorry.
And the abstract. Can you read the first sentence in the abstract?

Page 205

A. The benchmark dose method is the favored approach for quantitative dose-response analysis where uncertainty measurements are delineated between the upper and lower confidence bounds, or confidence intervals.
Q. Would you say that that research article is suggesting that the benchmark dose method is the preferred quantitative approach?
A. For these in vitro datasets using the covariant analysis approach where you end up with these potency ranks, I would agree that this is -- BMD is the favored approach as related here.
Q. And in this case, are you not also advocating that the benchmark dose method is the favored approach?
A. With these in vitro data, this --
Q. I'm not asking about in vitro data. I'm just asking if you're also advocating in this case that the benchmark dose method is the favored approach.

Page 206

MS. LOCKARD: I'm going to object with you arguing and interrupting the witness. I've let it go on a little bit, but he's entitled to give his answer. If it's not the question that you meant to ask, you can ask it again, but please don't cut the witness off.

Go ahead.

THE WITNESS: Could you please ask that question again?

BY MS. BOGDAN:

Q. The first question -- there was a run-on there, but is this research article advocating the benchmark dose approach?

A. This article is advocating a very specific use of the benchmark dose approach for analyzing in vitro data.

Q. So is this article, yes or no, advocating the benchmark dose approach?

MS. LOCKARD: Objection, form, asked and answered.

A. This article is using the benchmark dose approach on in vitro genetic

Page 207

toxicology data and showing the benefits of that for in vitro genetic toxicology data.

BY MS. BOGDAN:

Q. So this article is using the benchmark dose approach?

A. This article is using the benchmark dose approach on in vitro genetic toxicology data.

Q. And in this case, in your expert report, you're using the benchmark dose approach, correct?

A. I used the benchmark dose approach for the in vivo data in a different manner to how we use it here for these in vitro data. And in my report, where I based my judgment on my cancer-derived BMD using the quantum approach, using model averaging of that suite of models specific for cancer bioassay data analysis, which is very independent and different to this utility of it for in vitro genetic toxicology data, there's quite a large difference in those approaches.

MS. BOGDAN: If we could please

Page 208

pull up the next research article, Permitted Daily Exposure Limits for Noteworthy N-nitrosamines.

(Whereupon, Deposition Exhibit Johnson-15, Permitted daily exposure limits for noteworthy N-nitrosamines, by Johnson et al, was marked for identification.)

THE STENOGRAPHER: Exhibit 15.

BY MS. BOGDAN:

Q. Please let me know, Doctor, when you can see the exhibit.

A. I can see the exhibit.

Q. And when was this research article published?

A. It was accepted the 11th of May 2021.

Q. And in the Conflict of Interest section, which is towards the back of the article, three or four pages from the end...

A. Yes. I've got that.

Q. Was there a conflict of interest that you noted there?

A. There's a conflict of interest

Page 209

I stated in this section.

Q. Are you G.E.J.?

A. I am G.E.J. in this instance.

Q. And did you write that conflict of interest language?

A. I did write this conflict of interest language.

Q. And what did you write?

A. G.E.J., which is me, is a consultant who evaluates the risks posed by pharmaceutical impurities. His clients did not influence the content of this manuscript. The other authors do not declare any conflicts of interest.

Q. And what caused you to write that conflict of interest?

A. Because I was working on nitrosamines, and I was working on nitrosamines with Teva and GT, and also an expanded version of this, including confidence intervals around the PDE from my cancer-derived BMD were part of my risk assessment that were submitted for my expert opinion to Teva and GT.

So because of that, I saw that there was some level that should be disclosed in this Conflict of Interest section.

Q. Did you disclose in the Conflict of Interest section who -- what type of clients you had?

A. Pharmaceutical clients.

Q. I don't -- where did you write that you have pharmaceutical clients?

A. G.E.J. is a consultant who evaluates the risks posed by pharmaceutical impurities. His clients did not influence -- so I'm a consultant who evaluates. If I consult, then I work with the company to evaluate pharmaceutical impurities, which would be with a pharmaceutical company.

Q. Couldn't you be a consultant that evaluates the risks posed to the patients on behalf of the patients?

MS. LOCKARD: Objection, calls for speculation.

A. I do not know.

BY MS. BOGDAN:

Q. Is there anything in that

Conflict of Interest section that explains that you are working for the pharmaceutical companies?

A. I think it does, yes.

Q. Because it says that you are a consultant who evaluates the risk posed by pharmaceutical impurities?

A. That's my interpretation of that statement, yes.

Q. Did you consult anyone with regard to the language that you were choosing to use in the Conflict of Interest section?

A. I used this language based on the language I've seen from other pharmaceutical consultants in this area.

Q. And where had you seen this language used before, in this particular journal, Environmental and Molecular Mutagenesis?

A. I do not know where I found it previously, but I still think it is a good statement.

Q. Now, in this conflict of interest box, it also has another sentence

that precedes the ones that are highlighted here.

A. I'm not looking at your copy. Apologies. Okay, now I am. Can you rehighlight that section, please? Okay.

And what was your question again?

Q. The section or the statement that says: The other authors do not declare any conflicts of interest.

Do you see that?

A. I do see that.

Q. Did you have any specific conversation with the other authors regarding conflicts of interest or is that something they would independently report?

A. I do not know. They saw -- this was part of the document that all coauthors saw. That's my level of understanding here.

Q. With regard to Bhaskar Gollapudi who works for Exponent, do you know whether he had any conflicts of interest?

A. I do not know.

Q. Are you familiar with Exponent?

A. I'm not very familiar with Exponent, but I'm aware of some of their consultants.

Q. Who are you aware of other than Bhaskar Gollapudi?

A. There is two other coauthors on the ethylene oxide paper, although I can't recall their names, which also work for Exponent, for example.

Q. Have you ever worked for Exponent?

A. No. No.

Q. As the lead author, did you have a choice as to where this manuscript was being sent to be considered for publication?

A. Yes, I did have. Yes, I did.

Q. And did you send it to any other journals other than the Environmental and Molecular Mutagenesis journal?

A. No, I did not. In this area of applied genetic toxicology towards risk assessment, I realized this is the best journal for that particular topic.

Page 214

Q. And how did you go about selecting your coauthors for this publication?
A. These coauthors were people who contributed to a suitable extent within the HESI GTTC to be rewarded or to maintain coauthorship. And you'll see from the Acknowledgements section at the end, there was also other people that we had discussions with who didn't meet that criteria but did contribute along the lines of the suggested text in that Acknowledgements section.
Q. I understand that they were coauthors that -- were people who contributed to a suitable extent, but how did you identify them as being potential coauthors or approach them to begin with?
A. Within the HESI GTTC group, particularly on this topic, I do a large amount of the work, I did a large amount of the work, presented it to the HESI GTTC, and requested if people wanted to become involved in this research and could contribute to this research. That was the main way of getting

Page 215

these coauthors involved.
Q. And were you the one that came up with the idea or the topic for the research article?
A. As stated at the beginning of our conversation, I worked on this topic with a couple of regulatory friends to assess this. I realized it was an important topic, and decided to devise a publication around this topic, and then prepared this publication with these coauthors, and openly within the rest of the HESI GTTC, we created the publication, and then we submitted it to the -- the request itself from the journal and had it accepted.
Q. Isn't this publication involving exactly the type of work that you were doing for Teva with regard to your investigation into this case?
MS. LOCKARD: Objection, form, misstates testimony.
A. I see this publication as a case example, as an idea about what a -- this approach could look like to derive PDEs and

Page 216

how they could be compared to each other when you use the BMDLs from the cancer and the mutation datasets. Then in my report, which is different to this, I then started applying that in a risk assessment concept.
So the publication is not a risk assessment, and the report becomes a risk assessment through this extended analysis and application of information around the concentrations presented in that report. And there is a bit of a -- there is a large distinguishing factor along those lines.
Q. But with regard to the position that you're taking as to how to calculate the PDEs for NDMA and NDEA, isn't that set forth in this paper that was published in May of 2021?
A. The mutation data, we had a conceptual total for the PDE calculation that we put forward, and some discussion points about how that could potentially change for a real risk assessment from there onwards.
For the cancer-derived PDE

Page 217

where we did this off the BMDL lower, there's an extended version of this risk assessment, which I support, where you can do that calculation as well as calculating a BMD upper, so it wasn't complete in that respect.
Also, the composite uncertainty factors were really for the global population, but for a smaller population, you can actually adjust these uncertainty factors, even for the cancer bioassay data, to reduce them from 500 to 50, which would cause an order of magnitude increase on the PDEs in my report.
So there's -- this was more look at this, it can be done. Here's an example. This is not the finished product. My report is more this is how I am going to use this for a real assessment of risk in these patients.
Q. Did you submit your report in this case for publishing and peer review?
MS. LOCKARD: Objection, compound.
A. I submitted it to the clients,

Page 218

as it was a client -- client-facing document.
BY MS. BOGDAN:
Q. Did you submit your report in this case to a journal and ask that it be reviewed for publication?
MS. LOCKARD: Objection, form, compound.
A. I did not submit my confidential report for my clients to a journal.
BY MS. BOGDAN:
Q. Don't you cite in your report as authority your article that was published May 11th of 2021?
A. I cite my article, but I wouldn't use the term "as authority." I cite my article as the first approach of deriving PDEs using basic composite uncertainty factors using just the lower bound.
So, no, it wouldn't be as what's said in the paper is absolute. It's using the concepts from that and developing a more extended risk assessment in my report.
Q. Now, with your coauthors on

Page 219

this publication, you have Anthony Lynch, Jim Harvey and Julia Kenny, who all work for GlaxoSmithKline, correct?
A. That's correct.
Q. And GlaxoSmithKline produced Zantac from 1983 to 2017; isn't that correct?
MS. LOCKARD: Objection, form, speculation.
A. I do not know.
BY MS. BOGDAN:
Q. Do you know that GlaxoSmithKline manufactured Zantac?
A. I haven't looked into that.
Q. Are you aware that Zantac was recalled because of an issue with NDMA contamination?
A. I was aware that there was many pharmaceuticals that were recalled.
Q. And your conclusion that you're reaching in this 2021 publication with the PDE for NDMA, is that PDE higher than the acceptable intake limit that's been established by the FDA for NDMA?
A. It is higher than the

Page 220

acceptable intake based on the linear extrapolation, yes.
Q. And similarly with regard to the value that you have calculated for NDEA, is that permissible daily exposure for NDEA that you set forth in your publication higher than the acceptable intake that has been put forth by the FDA for NDEA?
A. That is correct. Theirs is based on linear back-extrapolation.
Q. And would the drug companies benefit from higher permissible levels of NDMA and NDEA allowed in pharmaceuticals?
MS. LOCKARD: Objection, form, speculation.
A. I do not know.
BY MS. BOGDAN:
Q. With higher limits of NDMA that are allowed, couldn't they sell pharmaceuticals that would have more NDMA in them -- in them?
MS. LOCKARD: Objection, form, speculation.
A. That could be one

Page 221

interpretation.
BY MS. BOGDAN:
Q. And similarly, with a raised allowed limit for NDEA, wouldn't that permit pharmaceutical companies to sell medicines with more NDEA in it?
MS. LOCKARD: Objection, form, speculation.
A. If the firm -- if the human exposure limit was higher, then a higher level of that substance would be shown not to increase human risk at those concentrations.
BY MS. BOGDAN:
Q. All right. So we went over the three authors, Lynch, Harvey and Kenny that work for GSK. You have other coauthors of Dobo and Kenyon, correct?
A. That is correct.
Q. And they both work for Pfizer; isn't that correct?
A. That is correct.
Q. And Pfizer manufactures Chantix, which was recalled this past summer due to an N-nitroso contamination.

Page 222

Are you aware of that?
A. I was not aware of that, and it's not articulated in this publication.
Q. And Pfizer also produced Zantac. Did you know that?
A. I did not know that.
Q. And Zantac has also been recalled because of an N-nitrosamine contamination issue.
Are you aware of that?
A. I'm aware that this issue has affected many companies and many drugs have been taken from the market.
Q. Now, more of your coauthors also work for pharma. You have Thybaud who works for Sanofi. Isn't that correct?
A. At the time she worked for Sanofi, and now she is retired.
Q. And Sanofi was another company that manufactured Zantac, which has been recalled because of NDMA contamination; isn't that correct?
A. I did not know that specifically. I did not know that

Page 223

specifically.
Q. And Sanofi has also manufactured irbesartan, which has been recalled because of NDMA and NDEA. Are you aware of that?
A. I was not aware of that, but realize that many companies, including the ones listed here, would have had similar issues.
Q. So except for Gollapudi, who works for Exponent, each of the other coauthors works for pharma, correct?
A. And Ryan Wheeldon with Swansea University, correct, with the pharmaceutical statement.
Q. And GSK, Pfizer -- I say "Sanofi," you say "Sanofi" -- they've all had issues with contamination of N-nitrosamines in their drugs?
MS. LOCKARD: Objection. That's not a question. Calls for speculation if it is.
BY MS. BOGDAN:
Q. On previous publications, some

Page 224

of which that we've already gone through, have dealt with -- if I can find them here -- benchmark dose -- let me find them here. I just put them down here -- mutations, regulatory decision-makings. There was an author by the name of Paul White. And so --
A. Yeah, I've met him.
Q. Yes? Right? Yes?
A. Sorry, I spoke over you. Can you repeat the question? I spoke over you.
Q. That's okay.
Paul White was a coauthor with you on several of these earlier environmental and molecular mutagenesis publications, correct?
A. Correct. That is correct.
Q. Did you ask if he would be willing to coauthor the permitted daily exposure limits for the nitrosamine publication?
A. I asked for his contributions, and due to workload, he was unable to commit to coauthorship. You'll see from Acknowledgements that we acknowledged the

Page 225

discussions with Paul White in that section.
At this time, he was not a cochair of this HESI GTTC quantitative group with me. It was myself and Andreas.
Q. And when you say you asked for his contributions, meaning you asked him to be a coauthor?
A. Meaning we had discussions around the work. We had just written a paper on uncertainty factors that could be applied to the genetic toxicity PDE. Those discussions were useful. Those sorts of discussions.
Q. Other than work, did he give any other reason that he was unable to commit to being a coauthor?
A. No, that would be workload issues for Paul White.
MS. LOCKARD: Do you need something to drink?
THE WITNESS: Yeah, is there any more Coke or is that all downstairs?
(Comments off the stenographic

record.)
BY MS. BOGDAN:
Q. When was it when you were asked to not only serve as an expert for Teva but then to serve as an expert for all defendants in the case?
MS. LOCKARD: Objection, asked and answered.
A. As a response, we can see from the invoices it was when I changed from consultancy to reporting, when I was generating the report. I was made aware at that time that it was for the other clients, extended from Teva. That was beginning of 2021.
BY MS. BOGDAN:
Q. Is there something on the invoice that indicates to you that that is the timing of when that took place?
A. Yes. So in my 05-07-2021 invoice for 35 hours, the discussions around reporting moved me really from understanding the whole area as a whole and having discussions with Teva and GT to focusing on a

report for the client and the extended board of clients.
MS. BOGDAN: Could we pull up the retainer letter, please, between Greenberg Traurig and Dr. Johnson.
(Whereupon, Deposition Exhibit Johnson-16, 6/8/21 Greenberg Traurig Letter, was marked for identification.)
THE STENOGRAPHER: Exhibit 16.
BY MS. BOGDAN:
Q. Doctor, do you want to let me know when you see that?
A. I see that.
Q. Oh, okay. I was just waiting. I didn't know if it was taking time for it to load, so...
Do you recognize that correspondence?
A. I do recognize that correspondence.
Q. And when did you receive this correspondence relevant to when you were asked to be an expert on behalf of all

defendants?
A. I do not know.
Q. Was it after you were asked to be an expert on behalf of all defendants?
MS. LOCKARD: Objection, form, asked and answered.
THE WITNESS: Yes.
A. I do not know.
BY MS. BOGDAN:
Q. Referring you to the first paragraph of the letter, it says a couple of sentences down: This letter will confirm our agreement to retain you as a(n) consultant/expert in connection with the above-styled litigation on behalf of Teva.
Do you see that sentence?
A. I see that sentence.
Q. Did you receive any type of similar letter from Greenberg Traurig after you were asked to serve as an expert on behalf of all defendants?
MS. LOCKARD: Objection, form. It's confusing.
A. I do not know. Contracts are

done through Swansea Innovations.
BY MS. BOGDAN:
Q. When you say contracts are done through Swansea Innovations, is there a separate writing that Swansea Innovations has with clients in order to hire you as a consultant or expert?
A. Could you say that again, please.
Q. You answered the last question where you said: I know contracts are done through Swansea Innovations.
So is there a separate writing that Swansea Innovations has that would pertain to your work as a consultant, slash, expert for Teva?
A. I understand now.
They do not. They would have this. That's my understanding.
Q. Now, in this letter it indicates on the second page that materials for your initial review would be sent to you separately via secure FTP, which is the first sentence on the second page.

Page 230

Were materials sent to you to review?
A. This -- I think they refer to a list of materials that were sent to me, and yes, they were sent to me.
Q. And are those included in your list of materials considered?
A. Yes.
Q. And then down further on that page, there's a paragraph that starts "Please note." Can you read that sentence, please.
A. Please note we are not asking for any sort of written report or written work product at this time. Once you have completed your review of the initial materials, please call me to arrange a convenient time when you can discuss your opinions on the case.
Q. And did you follow that instruction?
A. I was compiling a report was my understanding.
Q. And when did you start to compile the report?

Page 231

A. I don't know precisely the answer to that.
Q. Can you provide an estimate with regard to when you started the report relative to when you finished it?
A. I cannot.
Q. You cannot state how many months you were working on the report?
A. Not precisely.
THE WITNESS: May I ask for a break to get another bottle of Diet Coke?
MS. LOCKARD: Is this a good time, Rosemarie?
MS. BOGDAN: Sure. We can take a five-minute break.
THE VIDEOGRAPHER: Going off the record. The time is 3:20 p.m.
(Recess taken, 3:20 p.m. to 3:34 p.m. BST)
THE VIDEOGRAPHER: Back on the record. The time is 3:34 p.m.
BY MS. BOGDAN:
Q. With regard to the research

Page 232

article entitled Permitted Daily Exposure Limits for Noteworthy Nitrosamines, who funded the work for that study?
A. It was done independently of research funding. It was using published data that we reanalyzed and put forward, but due to my work with GT and Teva at that time, I acknowledged in the Conflict of Interest section that statement.
MS. BOGDAN: If we could please pull that exhibit up. It's the research article entitled Permitted.
And what exhibit number has this been marked?
TRIAL TECHNICIAN: This is, I believe, 14 of our number, so it was marked as Exhibit 15.
BY MS. BOGDAN:
Q. Directing your attention to the first page where it says Funding Information on the left-hand side?
A. Okay. Yes, I can see that.
Q. What does it say there?
A. Baxter International Inc.

Page 233

Q. And what type of company is Baxter?
MS. LOCKARD: Objection, form, ambiguous.
A. From my understanding, it is a medicinal product company.
BY MS. BOGDAN:
Q. As the lead author, did you go about acquiring the funding for this research article?
MS. LOCKARD: Objection, vague.
A. This Baxter International Incorporated funding was used by Ryan Wheeldon to pay for his tuition fees during his Ph.D.
BY MS. BOGDAN:
Q. So it was his tuition fees and then he spent his time contributing to this paper, and that's what that funding information indicates?
A. That's the entirety of that. That's what that funding indicates.
Q. Who paid you for your time in writing and authoring this research article?

Page 234

A. This was something I did off my own back in my own time with the HESI GTTC. I contribute my time without receiving additional funding because this is my research interest.

This particular topic I've been working on my whole academic life, and I put in a lot of time on that basis without receiving funding.

But I'll state it again. Because of the interest and link to my clients, Teva and GT, I acknowledged that there was that conflict of interest there. So no funding from other sources. I hope that statement was clear.

Q. Did you use any of the knowledge you had gained doing your consulting work on this litigation regarding nitrosamine contamination in valsartan drugs when writing this research article?

MS. LOCKARD: Objection, form, vague.

A. I did not. From day one when I was made aware of this issue of the

Page 235

substance or these substances that were carrying out adducts and mutations through the mechanism that I understood entirely, I had the knowledge at hand to be able to write this pretty much from day one.

BY MS. BOGDAN:

Q. When did you begin working on this research article?

A. The concepts contained within the research article would date back to that Informa Impurities conference where I put forward the concept of it and then refined that and my understanding of it throughout, and then preparation of the manuscript. PI cannot give you dates and times, but it was in a -- I worked on it when I could and prepared it and submitted it as you've seen.

Q. Did you start work on this before you were retained to be a consultant for Teva in this litigation?

A. As stated, I worked on this concept and did a lot of analysis before that, correct.

Q. When did the first draft of

Page 236

this research article come into being?

A. I do not know.

Q. Was it in 2018?

A. I don't think I'm that efficient. I don't think so.

Q. Was it in 2019?

A. I do not know.

Q. Did this go out for peer review?

A. It did go out for peer review.

Q. Did it get any critical comments as part of the peer-review process?

A. It got some detailed peer-reviewed comments, some critical, which we addressed and overcame and changed accordingly. Some supportive. Same from the editor as well. We addressed the comments, and they were happy, we were happy. The editor who works at Health Canada supported that those changes were accepted, and the peer-review process was adhered to, and the editorial process as well.

Q. And what were the changes that were made in response to the critical

Page 237

peer-review comments?

A. I do not know.

Q. Do you remember the topic areas of the critical peer-review comments?

A. I do not. Mostly stylistic, around wording, I think.

Q. How many research articles have you authored with a coauthor affiliated with Exponent?

A. I do not know.

Q. Would you say there's been more than five?

A. I do not know.

MS. BOGDAN: Could we please pull up exhibit Business Ethics Magazine by FairWarning.org.

(Whereupon, Deposition Exhibit Johnson-17, Business Ethics Article, Legal Scrapes Turn to Science-for-Hire Giant Exponent, was marked for identification.)

THE STENOGRAPHER: Exhibit 17.

THE WITNESS: Not yet.

TRIAL TECHNICIAN: Give me one

Page 238

moment. It's giving me some trouble. Hang on.

There we go, should see it now.

THE WITNESS: I can see it now, Exhibit 17 is loading. It's on my screen.

BY MS. BOGDAN:

Q. Are you aware of articles like this criticizing Exponent and the work that it does on behalf of industry?

A. I'm not aware of this article or similar ones.

Q. Directing your attention to the last statement on the first page, which reads: It's a go-to destination for major industries with liability problems, even as it is derided by critics as hired -- as a hired gun whose findings are for sale.

Do you see that?

A. I see that.

Q. Are you aware of allegations like that regarding Exponent?

A. No, I'm not.

Q. If we could turn to page 3 --

Page 239

or actually, page 2 of the document. Directing your attention to the last paragraph.

A. I can see it.

Q. Okay. Where it reads: Opponents say Exponent's scientists and engineers routinely bend conclusions to the needs of clients, noting that the company in the 1990s supported the tobacco industry in denying the lung cancer risk of secondhand smoke.

Were you aware of that allegation?

MS. LOCKARD: Objection, vague.

A. I'm not aware of that statement from the 1990s.

BY MS. BOGDAN:

Q. And with regard to the second statement: The firm's forte, they say, is doubt science, muddying the waters by attacking research showing evidence of harm, highlighting or exaggerating scientific uncertainties about health hazards, and calling for more research to delay action.

Page 240

The result, critics say, is a pro-industry imprint on scientific literature.

Are you aware of those types of allegations against Exponent?

A. I'm not aware of those types of allegations towards Exponent.

Q. And if I could direct you to page 5, this is the middle paragraph.

A. I think I can see it, next to a picture of someone; is that correct?

Q. That's a picture of Roger L. McCarthy, a former CEO and chairman of Exponent.

A. I see that.

Q. What it says is: The drive for repeat business is not the only reason. Clients who fund research often own the data that is generated and must approve the publication of results, said Roger L. McCarthy, a former Exponent CEO and chairman, who retired from the company in 2009 and agreed to speak with FairWarning.

Are you aware of those statements of the former CEO of the company?

Page 241

A. This is the first time I have seen that statement.

Q. We can take that down.

Would it be fair to say that you've authored more than five articles with Exponent coauthors?

MS. LOCKARD: Objection, asked and answered.

A. I do not know.

BY MS. BOGDAN:

Q. Well, how many articles have you authored with Gollapudi?

A. I do not know, but if you would wish me to count them, that could be another question.

Q. Not here.

We have the Permitted Daily Exposure Limits For Noteworthy Nitrosamines, that was with Gollapudi, right?

A. Yes. Can you give me the dates when we're going through these, please?

Q. Sure. That was accepted May 11th of 2021.

A. Excellent. I agree that is one

Page 242

with Bhaskar Gollapudi.
Q. Genotoxicity as a Toxicologically Relevant Endpoint to Inform Risk Assessment: A case study with ethyl oxide. That was September 4th of 2020. That was with Gollapudi, correct?
A. That is correct.
Q. Here's one from 2016, Next-Generation Testing Strategy for Assessment of Genomic Damage: A conceptual framework -- (audio malfunction) --
(Clarification requested by the stenographer.)
BY MS. BOGDAN:
Q. -- and considerations.
A. The first author of that one, please?
Q. Dearfield, Kerry Dearfield.
A. Yeah, that's correct. He's ex-EPA and USDA, thank you.
Q. Here is one from 2014, Derivation of Point of Departure Estimates in Genetic Toxicology Studies?
A. Yeah, that was me, first

Page 243

author.
Q. Here's another one, Mutation as a Toxicological Endpoint for Regulatory Decision-Making. That was published online, October 10th of 2019?
A. Yeah, with Bob Heflich from FDA as first author. I see that, yes.
Q. Yeah. All right. And those are the ones I have.
A. Okay.
MS. BOGDAN: If we could put up the article entitled Tolerability of Risk: A commentary on the nitrosamine contamination issue.
(Whereupon, Deposition Exhibit Johnson-18, Tolerability of risk: A commentary on the nitrosamine contamination issue, by Elder et al, was marked for identification.)
BY MS. BOGDAN:
Q. Are you a coauthor of that study?
THE WITNESS: Yeah, it's not appearing as an exhibit yet. Is that

Page 244

Exhibit 18?
MS. BOGDAN: This is going to be marked a new exhibit. I don't think it's been marked yet.
THE WITNESS: Okay. I can see it, thank you.
MS. BOGDAN: And it has been marked as Exhibit 18 for identification?
THE STENOGRAPHER: Yes.
BY MS. BOGDAN:
Q. Are you a coauthor of that study?
A. I'm a coauthor of this commentary, yes.
Q. And did you disclose a conflict of interest in this commentary that was published in the Journal of Pharmaceutical Sciences?
A. We did not, no.
Q. And this commentary is about the nitrosamine contamination issue in pharmaceuticals, correct?
A. It is a commentary on the

Page 245

nitrosamine contamination issue, correct.
MS. BOGDAN: If we could please pull up the Journal of Pharmaceutical Sciences introduction, types of articles and declaration of interest exhibit, please.
(Whereupon, Deposition Exhibit Johnson-19, JPharmSci Declaration of Interest Policy, was marked for identification.)
THE STENOGRAPHER: Exhibit 19.
BY MS. BOGDAN:
Q. And if you could please go to page 4 of that exhibit.
A. Okay. Page 4.
Q. And under Declaration of Interest --
A. I can see that.
Q. -- it says: All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence, bias, their work. Examples of potential competing interests include

Page 246

employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

Do you see that?

A. Yes, I see that.

Q. And authors must disclose any interest in two places: A summary declaration of interest statement in the title page file, or the manuscript file. If there are no interests to declare, then please state this: Declarations of interest, none.

Do you see that?

A. I do see that.

Q. This is the declaration of interest for the Journal of Pharmaceutical Sciences where you published general commentary entitled Tolerability of Risk: A commentary on the nitrosamine contamination issue, is it not?

A. That is the journal associated with that publication, yes.

MS. BOGDAN: We can take that

Page 247

exhibit down, please. Thank you.

I'm trying to get my spot here. Okay. If we could please pull up the FDA Laboratory analysis of valsartan products.

(Whereupon, Deposition Exhibit Johnson-20, Laboratory Analysis of Valsartan Products, was marked for identification.)

THE STENOGRAPHER: Exhibit 19.

TRIAL TECHNICIAN: That's Exhibit 20, Mike.

BY MS. BOGDAN:

Q. Let me know, Doctor, once it's up on your screen.

A. It's just come up on my screen.

Q. Do you recognize that document?

A. I recognize the table and this document, yes.

Q. What do you recognize that to be?

A. I recognize this to be the FDA analysis as stated in the text of these substances in the finished product, drugs and

Page 248

APIs.

Q. All right. Let's -- do you have a hard copy in front of you so you can see the second and third page?

A. I have a hard copy in front of me. I didn't catch the second statement.

MS. LOCKARD: He has a hard copy. Let me just make sure it's the same thing you have.

MS. BOGDAN: If you could just move this to the second and third page so that the witness can see the whole exhibit.

MS. LOCKARD: Yes, it appears to be the same as your exhibit.

BY MS. BOGDAN:

Q. Did you review this document as part of your investigation into this matter?

A. I reviewed it and included the metrics in my report.

Q. Now, when you say you included the metrics, what are you referring to?

A. Oh, I included the table, including the numbers and details into my

Page 249

report, as far as I'm aware.

Q. What information does the table have in it?

A. It has a row of columns. We've got Company, Product Name, Lots Tested, NDMA levels and NDEA levels within those lots tested from the different companies in a different size and different tablets.

Q. And did you put this information directly into your report?

A. I put this directly into my report. I also included an additional modification of the midpoint based on these numbers, where appropriate.

Q. And when you say you added the midpoint, why did you do that?

A. I do a lot of statistical analysis, and I like to have as much information for metrics as possible. The numbers were not available to carry out means and standard deviations, and the midpoints are calculated as another useful metric for me to use in my analyses.

Q. So you did the midpoint of the

lots that were tested as shown in the table?
A. Yes.
Q. And how many lots approximately were tested for each of the manufacturers' products?
A. They vary. The lots that were tested according to this table, average -- there was lots of three lots tested for certain companies. There's some where six lots were tested. There's variation in the number of lots tested.
Q. Do you know how many lots of -- for example, let's take Aurobindo at the top.
Do you see that at the very top?
A. I see that at the very top.
Q. And you see amlodipine, 10 milligrams/valsartan -- valsartan, 320 milligrams?
A. Yes, I do see that.
Q. Okay. Do you know how many lots Aurobindo actually made of that medication during the relevant time period when the contamination took place?

A. I do not know that number.
Q. Did you make inquiry to find out the number of lots that were manufactured?
A. I did not inquire to that, but the available data from these companies on the lots tested was made available to me, but I did not request the number that you've just suggested.
Q. So you didn't request for any of the companies that are listed in this exhibit information about the total number of lots they actually manufactured of each of these products?
A. No. My acceptance that the FDA is a regulatory body that did this analysis and presented a useful body of information was enough for me to present this table as it was.
Q. Well, you testified that you like to have as much information for metrics as possible; is that true?
A. Where suitable, lots of metrics can be very useful, and access to that

information can be useful.
Q. Did you ask for the information regarding the test results that the individual manufacturers had for the NDMA and NDEA levels in their product based on the testing they had performed?
A. Yes, and I was provided with that information, had access to that information, and saw that there was no real issue in going with these numbers that I presented here from FDA to the final product.
Q. Did you create any type of writing or chart comparing the values that you looked at for the defendants' internal testing results with the results that are reported --
A. I did not.
Q. -- on this exhibit?
A. I did not. Apologies for speaking over you.
Q. No, that's -- we have a little bit of a delay going on. It seems to have gotten a little worse, so I'll try to make sure I have a real pause before I start

speaking again.
If you reviewed the internal test results from the manufacturer's testing of their product, then wouldn't you have had information regarding the lots that were manufactured?
A. That information -- I was -- the interest from those lots from my perspective was upper limits and whether they exceeded the upper limits in this final product presented in the FDA table. And from my discussions and observations from that information, I was happy to go with this FDA table.
Q. And did you systematically go through each of the manufacturers listed on the left to see if their internal test results showed levels that were higher than what was reported by the FDA on this table?
MS. LOCKARD: Objection, form, ambiguous.
A. I had this information to hand. It was available for my consideration, and I did consider that those -- those data from

Page 254

the different companies.
BY MS. BOGDAN:
Q. And how many internal test result documents did you review?
A. I do not know.
Q. Did you review hundreds of internal test results from the company showing the levels of NDMA and NDEA in their products?
A. I do not know.
Q. Can you point me to where on your list of materials considered internal testing data is for the companies? Do you have a --
MS. LOCKARD: I'm turning to the corporate document section, and I'm not pointing anything out.
BY MS. BOGDAN:
Q. Doctor, did you make any note on your list of materials considered which of those corporate documents you're referring to having reviewed with regard to the internal testing data from the companies?
A. I --

Page 255

MS. LOCKARD: You can take time to look through that.
THE WITNESS: Okay.
MS. LOCKARD: I just put it in front of you.
(Document review.)
A. I think it comes under the testing results, to -- say, Mylan API testing results on, say, page 19. Maybe other documents with similar titles as well. As I've suggested, I've not made notes as to which of these documents I've reviewed. I reviewed them as and when they were provided by me -- provided to me.
BY MS. BOGDAN:
Q. Did you make any efforts to take the midpoint for the internal test results that the companies arrived at when doing NDMA and NDEA testing of their products?
A. I did not with those. My interest was in upper limits from those documents.
Q. If your interest was in upper

Page 256

limits, why did you calculate the midpoint?
A. For additional information from the FDA analyses.
Q. When calculating something like the midpoint of testing values -- strike that.
How did you make a determination that the test results that the FDA reported were representative of all of the product that each of the defendants had manufactured over the time period the contamination took place?
A. I made the determination that the FDA was the regulatory body in charge of risk assessment for these batches within the U.S., and that this was a suitable data source.
Q. And this data source reports the test results on between one and six batches of product per type, per manufacturer, correct?
A. That is correct. And it was analyzed in a consistent manner by the same people to enable these comparisons as well.

Page 257

Q. However, if there were hundreds of batches and lots that were made, wouldn't it be better to have information regarding all of the test results as opposed to one, two, three, four, five or six for a particular batch?
A. In science and risk assessment, decisions have to be made at a point to make a decision on a certain dataset. You don't need infinite data sources unless you're aware of something that extremely deviates from the data presented here. And to my knowledge to date, that has not been presented, and these are robust to allow us to make this decision.
Q. You used the word "robust." What makes these results robust if the lots tested were either one, two, three, four, five or six lots in comparison to hundreds that were made?
A. My term of "robust" would be from -- analyzed by the FDA using extremely top-end machinery to get very precise results in a way that they're happy to carry out a

risk assessment on. I would use here -- that was expansion on my use of the term "robust."

Q. You're appearing as an expert on behalf of the defendants in this litigation, correct?

A. Yes, that is correct.

Q. Do you have any reason as you sit there to believe that their own testing of the product that they manufactured results were incorrect or wrong?

A. I do not have any reason to make that assumption, and I'm not an expert in testing samples such as these using techniques such as mass spectrometry.

Q. Through your investigation into this matter, did you learn any information that would lead you to believe that the defendant's own testing of its product for NDMA or NDEA was flawed?

A. I did. I looked at the information, had discussions, and found no evidence that the analyses were flawed.

Q. Did you request test results from either ZHP, Prinston or Solco regarding

the product that they manufactured?

A. I'm quite confident that I've got that information -- I've had that information passed to me and highlighted as being the information from those companies throughout this time.

Q. And did you record that information in your report?

A. The information that I have accessed and have considered, these would be in the list of materials provided or whatever term we have for that long list.

Q. And that list is completely comprehensive of what you reviewed, correct?

A. As far as I'm aware, that is correct.

MS. BOGDAN: If we could please pull up the exhibit which is the general advice letter of the FDA.

(Whereupon, Deposition Exhibit Johnson-21, USFDA General Advice Letter, was marked for identification.)

THE STENOGRAPHER: Exhibit 21.

MS. LOCKARD: What number exhibit would this be?

MS. BOGDAN: 21, I believe.

THE WITNESS: After this set of questions, can I request another short break? Getting -- another short break, please.

MS. BOGDAN: Why don't we actually, if you would like a break, take one before we start asking questions about this document. I'd rather not break while I'm working with the document. So does that work for you?

THE WITNESS: Works for me.

THE VIDEOGRAPHER: Going off the record. The time is 4:17 p.m.

(Recess taken, 4:17 p.m. to 4:32 p.m. BST)

THE VIDEOGRAPHER: We're back on the record. The time is 4:32 p.m.

BY MS. BOGDAN:

Q. Dr. Johnson, is this exhibit, which is the general advice letter from the

FDA, now up on the screen?

A. Yes, it is. Could you make it larger -- or I could open it -- I could open it in exhibits.

Q. I think it was just made larger. Can you see it now?

A. I can see it now, that's great.

Q. Yeah. Did you review this letter as part of your investigation into this matter?

A. I can't recall this specific letter.

Q. All right. Well, this letter in the first sentence, do you see it's referring to angiotensin II receptor blockers, ARB?

A. Yes. Yes, I can see that.

Q. Is valsartan an ARB?

A. To my understanding, it is.

Q. If we could go down to the third paragraph, could you read the first sentence in the third paragraph?

A. Tell me the first word of that sentence, please.

Page 262

Q. "Nitrosamine."
A. Okay. Reading this out: Nitrosamine compounds are potent genotoxic carcinogens in several nonclinical species and are classified as probable human carcinogens by the International Agency for Research on Cancer, brackets, IARC.
Q. Do you agree with that statement?
A. I agree that IARC classify nitrosamine compounds as potent genotoxic carcinogens in many instances, and that they are probable human carcinogens.
Q. Are NDMA and NDEA nitrosamine compounds?
A. Yes, they are nitrosamine compounds, NDMA and NDEA.
Q. Do you agree that NDMA is a potent genotoxic carcinogen?
A. The term "potency," from this definition -- it's taken from the TD linear back-extrapolation for potency. So I agree that they are genotoxic carcinogens, but the definition they use for "potent" relies on

Page 263

the linear back-extrapolation approach, which I have issues with.
Q. Do you agree that NDMA is a genotoxic carcinogen?
A. I believe --
MS. LOCKARD: Objection, form, vague.
A. -- NDMA has been shown to be a genotoxic carcinogen in animal studies, yes.
BY MS. BOGDAN:
Q. Do you agree that NDEA is a genotoxic carcinogen?
MS. LOCKARD: Objection, form, vague.
A. I believe that NDEA is a genotoxic carcinogen in animals too.
BY MS. BOGDAN:
Q. Do you have an opinion whether NDMA is a human carcinogen?
A. I believe that that has not been shown to date through the data as I've seen.
Q. Do you know what an RCT is?
A. Potentially. Could you expand

Page 264

on that phrase, please?
Q. Randomized controlled trial?
A. I understand what a randomized controlled trial is to a certain level, but I do not carry out analysis on clinical trials.
Q. In your research into this matter, have you found any RCTs on humans to determine whether NDMA is a human carcinogen?
A. I have not seen data to that regard to show that humans have increased levels of cancer following exposure to NDMA.
Q. The same question as it pertains to NDEA. In your research into this matter, have you found any randomized controlled trials on humans to determine whether NDEA is a human carcinogen?
A. I have not seen any clinical trial, randomized controlled trial studies on NDEA in humans to show that it's a human carcinogen. I have not seen those data.
Q. Do you know whether it would be ethical to conduct human trials using NDMA or NDEA to determine if they're carcinogenic in people?

Page 265

A. It's more that they would not be practical. That's why we go with the animal studies for such analyses for genotoxic impurities.
Q. And why wouldn't they be practical?
A. The rodent carcinogenicity studies, these are lifetime studies. To do a lifetime study in a human would take a lot longer to generate the data, over, say, a 70-year period, then sacrifice the human at the end of that and carry out pathology on their organs, not practical. Two years, much better than 70 years.
Q. Are you familiar with IARC?
A. I am. I have a familiarity with IARC that carry out hazard assessments, yes.
Q. And were you familiar with them before your investigation into this case?
MS. LOCKARD: Objection, form, the word "investigation."
A. I was aware of IARC before this -- I've been aware of IARC for many

Page 266

years.
BY MS. BOGDAN:
Q. In the field of toxicology, is IARC looked to as a resource with regard to evaluating the carcinogenic risk of chemicals to humans?
A. No, it is not. It is to define the hazard identified by these substances and not the risk.
MS. BOGDAN: If we could please pull up the exhibit IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans.
(Whereupon, Deposition Exhibit Johnson-22, 1978 IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, was marked for identification.)
THE STENOGRAPHER: 22.
TRIAL TECHNICIAN: I don't see this.
MS. BOGDAN: It's dated 1978, the original one.
THE WITNESS: I have yet to

Page 267

receive it as an exhibit. Is it 22? That may have just popped up. Is this Exhibit 22?
MS. LOCKARD: Should be.
THE WITNESS: Right. It has come up, very gray. I can see it, yes.
BY MS. BOGDAN:
Q. What is the title of that document?
A. IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans.
Q. So does the title of that document indicate to you that IARC monographs are used to evaluate the carcinogenic risk of chemicals to humans?
A. This title, presented in 1978, was before the IARC announced that they were actually a hazard-based organization more recently. They do not talk about concentrations and human exposure limits, rather, yes/no, and categorizing them in human carcinogen, probable carcinogen and so

Page 268

on, which is not risk. It's hazard.
Q. And evaluating whether or not a chemical is a hazard to a human, would one of those things or attributes that would make it a hazard be that it's carcinogenic?
MS. LOCKARD: Objection, vague.
A. That would be one of the aspects of hazards, as long as the data abided to the OECD guideline on the cancer bioassay for which these decisions could be made. And this monograph predates the OECD guideline for the cancer bioassay.
BY MS. BOGDAN:
Q. Now, when you're talking about the OCD -- or OECD guideline for cancer bioassay, you're talking about the guidelines to run an animal test, correct?
A. A very specific animal test where the species are defined, with rodent being the preferred and very specific criteria on study design.
Q. If we could go back to the previous exhibit, which was the general advice letter from the FDA, please. The next

Page 269

sentence that begins "In fact," do you see that?
A. The one which you're highlighting beginning "In fact," yes, I see that.
Q. So that sentence reads: In fact, N-nitroso compounds are identified as a cohort of concern in internationally harmonized guidance, ICH M7, Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.
Do you see that sentence?
A. Yes, I see that sentence.
Q. Are you familiar with the concept of "cohort of concern" that's referred to in that sentence?
A. I'm very familiar with that term.
Q. What does that term mean?
A. For genotoxic impurities, they're of high importance, and that's why the ICH M7 guideline really was prepared.
Within that, they came up with

Page 270

a concept, an applied concept called the threshold for toxicological concern, where they assessed all of the data from the cancer potency database that used to reside in Berkeley in the GOLD database that now resides at Lhasa, took all of that information, took the harmonic means from the TD50s from the cancer bioassay dose-response data, did a 1-in-100,000 level of risk calculations or linear back-extrapolation, one of the things that I push against with the PDE based on threshold assumption.

And from the calculation for the threshold of toxicological concern, a proportion of the nitroso compounds were shown to be more potent, the 1 in 100,000 at the concentration of 1.5 micrograms per day in humans. And that's all that means.

Q. And the ones that were shown to be more potent, do those include NDMA and NDEA?

A. That was not prescribed, but the regulatory bodies have done the acceptable intake space on those compounds.

Page 271

Q. And the regulatory bodies followed the TD50 linear extrapolation approach to come up with the acceptable intakes; is that correct?

A. They did, yes.

Q. And when we're referring to regulatory bodies, the TD50 linear extrapolation approach is the one that's followed by the FDA, correct, for NDMA and NDEA?

A. It is the one that's followed in order to generate the acceptable intakes presented for NDMA and NDEA.

Q. And the EMA also followed the TD50 linear extrapolation approach to come up with the acceptable intakes for NDMA and NDEA?

A. That is correct. On this reactive response, they needed to carry out a very quick and harmonized approach that global regulatory bodies could do, where you could get the harmonic means from the TD50, CPDB database, and do a very simple linear back-extrapolation, and come up with these

Page 272

acceptable intakes across the global platform to generate these acceptable intakes.

Q. So the TD50 linear back-extrapolation methodology for NDMA is accepted by the FDA, correct?

A. It is accepted by the FDA, and so is permitted daily exposure, as stated in the ICH guidance.

Q. And the TD50 linear back-extrapolation methodology for determining acceptable intake of NDEA is accepted by the FDA, correct?

A. That is correct. And they used the linear back-extrapolation from the TD50 to generate the accepted intake, but within the guidance, there's also an option for other risk assessment approaches, including the PDE.

Q. However, the FDA did not elect to use any of those other approaches. They used the linear back-extrapolation approach using TD50 and the harmonic mean, correct?

A. Correct. To that time, in this very reactive procedure, they -- they did

Page 273

make that decision, and then in the future with further nitrosamines, when increased information about mechanism of action, dose response is included, then there will be more options for the PDE as the science catches up.

Q. The next sentence reads: ICH M7 recommends that known mutagenic carcinogens such as nitrosamines be controlled at or below the acceptable cancer risk level.

Is that what the ICH M7 recommends to your knowledge?

A. At the current time, to my knowledge, that's the recommendation.

Q. Due to their known potent carcinogenic effects, and because it is feasible to limit these impurities by taking reasonable steps to prevent or eliminate their presence, the FDA has determined that there is no acceptable specification for nitrosamines in ARB, API and DP.

Is that your understanding of the FDA's determination?

Page 274

MS. LOCKARD: Objection, form.
A. Yeah, from this statement I've read and see that that's the statement from the FDA, yes.
BY MS. BOGDAN:
Q. And in that sentence, if we could highlight it, what does API stand for?
A. From my understanding, it means active pharmaceutical ingredient.
Q. And what do the initials DP stand for?
A. I'm unsure.
Q. Have you seen the initials DP refer to drug product before?
A. I haven't seen it abbreviated to DP. I see finished product, FP, more by my colleagues in this area.
Q. And when someone takes a medication, is the API the actual active ingredient, the amount of the -- excuse me -- the amount of the active ingredient in the tablet, meaning if you're taking valsartan and it's 320 milligrams, it would be the valsartan 320 milligrams that's contained in

Page 275

the tablet?
MS. LOCKARD: Objection, form.
A. Could you restate that question again, please.
BY MS. BOGDAN:
Q. You said that API is the active pharmaceutical ingredient, correct? Active pharmaceutical ingredient. How does that relate to a tablet that somebody takes?
A. This isn't my area of expertise, but my understanding is the active pharmaceutical ingredient is combined with other substances for, say, different delivery around the -- around the human in this instance. So it's a part of the drug but not the complete construction of the final drug, or DP, in this instance.
Q. Are you an expert in pharmaceutical manufacturing?
A. I'm not an expert in pharmaceutical manufacturing.
MS. BOGDAN: We can take that down.
///

Page 276

BY MS. BOGDAN:
Q. What is a mutagen?
A. The definition in Europe is that a mutagen is a substance that causes gene mutations, and we assess for that with mutagenicity tests in genetic toxicology. There's some use in the U.S. by different regulatory bodies that a mutagen covers all types of genotoxicants.
Q. Do you differentiate between the term "genotoxicants" and "mutagens"?
A. In -- I do, in this instance, particularly when working with very important substances where the mechanism of action is mutation. We understand the mutation mechanism. Definitely use the term "mutagen."
Q. Does a mutagen change the DNA sequence?
A. At the correct dose, the mutagen can cause adducts, those DNA adducts at certain places within the DNA, such as the O6 position of guanine, which these compounds can target, can leave an alkyl group on those

Page 277

specific positions in the DNA.
If those are left unrepaired by the high levels of enzymes such as MGMT, and if they're in a region where upon replication they can be miscoded to another base, so upon replication with the O6-alkylguanine lesion, it would go from GC to AT.
And then that would go from being an adduct to that specific area having a mutation, and that mutation would have been caused by that adduct.
Q. So in order to have a mutation, the change in the DNA has to replicate, correct?
A. In order for the adduct to go into a mutation, it has to be misrecognized as something else, and when it's misrecognized as something else, another base gets put opposite it, and that happens at the DNA replication part of the cell cycle.
Q. How do mutations lead to cancer?
A. Mutations can lead to cancer if those mutations are in the coding region of

Page 278

DNA. Say 95% of our DNA is junk DNA that wouldn't have a coding gene. Then also to say the 25,000 other genes that we have, there's some that are associated with cancer.

The broad term for those types of genes are "oncogenes." If an oncogene is upregulated through mutation, that leads to increased proliferation, the hallmark of cancer.

If a tumor suppressor gene -- if there's a mutation which causes a tumor suppressor gene to be silenced, then things like DNA repair are not triggered. So if there's mutations in this very specific region of DNA and they're not picked up from the DNA repair machinery, then they can lead to cancer.

And a few of those genes -- say most cancers would need, say, three to six genes to be mutated before the cancer would ensue, then at those concentrations of -- those levels of mutation, those levels of mutation could lead to cancer. That's my explanation of it.

Page 279

Q. And is NDMA a mutagen?

A. NDMA is an alkylating agent and it acts at those positions -- at that position of guanine, which I mentioned. And when we carried out mutation testing on NDMA, we saw that it was a mutagen in the genetic toxicology test system for mutation.

Q. Is NDEA a mutagen?

A. NDEA is a mutagen through a very similar mechanism acting at the same sort of adduct spectrum, mutation spectrum as NDMA as well.

Q. Are they both alkyline agents?

A. The term is "alkylating agent."

Q. Oh, I'm sorry. Yeah.

A. Alkylating.

Q. Okay.

A. So NDMA and the metabolite of NDMA can cause a CH3 group, which is a methyl group, and the broader term of a methyl group would be under an alkyl group. So that's the methylating part of that term.

And then NDEA could cause C2H5, which would be an ethyl group, and that's

Page 280

also under the blanket term of "alkyl."

So because of those substances acting via that mechanism for causing DNA adducts and then mutation, they can be termed "alkylating agents" because they provide an alkyl group to the DNA at certain concentrations.

Q. Now, I've heard that they can also, when they are metabolized into their reactive form, form an ion. Is that true?

A. The ion, from my understanding, the ion is the part with the methyl or ethyl group, depending whether it's NDMA or NDEA respectively. And that metabolite, that ion, is the active group of that.

And because that requires -- to get to that stage, requires metabolism specifically from cytochrome P450 enzymes, which are mostly found particularly at high levels in the liver, that activity of that ion causing those adduct mutations for these substances is clearly identified in the liver.

Q. Now, you mentioned the P450

Page 281

enzymes. Are they found elsewhere in the human body other than the liver?

A. They are found at much lower levels other than the liver. The liver's job is really to be a metabolic powerhouse, and because of that, the liver contains huge amounts, high levels of these cytochrome P450s than other organs, but as a residual, at very low levels, they can be found potentially in some other organs. But I'm not an expert on those levels in other organs.

Q. I was going to ask: Did you do research into where the cytochrome P450s exist in the human body other than the liver?

A. That was not part of my remit and part of my report. I was looking at the endpoints rather than the cytochrome P450 levels. Okay.

Q. What exactly were you asked to do when you were hired as a consultant by Teva in this litigation?

MS. LOCKARD: Objection, form, vague.

A. The exact remit of what I was -- what we discussed and what my report and risk assessment would include as supported by Teva and GT and later with the other defendants, at the time of initiation, because they had seen my presentation on the PDE in these different ways, it was very much: Can you expand on this report around PDEs and see how it applies to our situation.

Beyond that, it was built on what I've already done, what I already know, and see how it applies to this situation.

BY MS. BOGDAN:

Q. And when you say they had seen my presentation on the PDE, what presentation are you referring to?

A. This initiates from that Informa Impurities conference where I presented that work that we've discussed quite extensively already in Berlin where I had done the work with my regulatory colleagues, come up with some interesting findings, and presented them at that meeting.

And really, it was just an

extension of what do these PDEs look like when you apply your numbers to the situation. Yes.

Q. Who funded that original work you did that led to the presentation in Berlin, I believe you testified in 2018?

MS. LOCKARD: Objection, asked and answered and vague.

A. We discussed this extensively earlier to my recollection, and again, it was not funded. It was really research exercise triggered from my work with my regulatory experts and then expanded upon to the HESI GTTC.

So I was not funded to carry out that initial work that was presented at that conference.

Q. Is NDMA genotoxic?

A. NDMA, in line with my description of the term "genotoxic," my description of the term "genotoxic" is in line with many of those experts in Europe where genotoxic is the all-encompassing power, the all-encompassing term for

mutagens, for clastogens, for antigens.

So under the blanket term of "genotoxic," mutagen becomes under that. And as I've already described, NDMA has been shown to be a mutagen in these in vitro and in vivo tests.

Q. And then the same question with regard to NDEA because we're dealing with both compounds here, Doctor.

Is NDEA genotoxic?

A. Within the same definition, within -- under the term, blanket term "genotoxic" is the term "mutagen," so because I've already discussed around NDEA being assessed and shown to be a mutagen in vitro and in vivo with the standard tests, then we can say it's a mutagen, and we can say it's a -- and it's genotoxic.

Q. And why are mutagens and genotoxins as far as chemicals a concern, if at all?

A. At the right concentration, at a high concentration, the genotoxicant or -- that would probably be something I'd talk

about chromosomal, structural damage or chromosome loss, but I want to talk about mutation because that's relevant here.

So we're trying to protect against increased levels of mutation by ensuring that high levels of mutagens and that people aren't exposed to them, because at high levels of mutagens, they cause mutation. High levels of mutation can lead to cancer at certain doses of a substance that is a mutagen.

MS. BOGDAN: Okay. Can we pull back up the next exhibit that was already marked, which was that IARC monograph.

TRIAL TECHNICIAN: Was that Exhibit 22?

MS. BOGDAN: I believe so. It's the one right after the FDA letter. It was the last exhibit we marked.

TRIAL TECHNICIAN: Okay.

MS. BOGDAN: No, that's not it. It's the one that had the gray cover,

the IARC monograph dated 1978.
(Technical comments off the stenographic record.)
BY MS. BOGDAN:
Q. Have you reviewed this document as part of your investigation into this case?
A. I've considered this document, but it didn't contribute to my decision because the data within this predate the guidance on how to carry out cancer dose-response analysis in animals and also predates the best cancer data in animals, which would be the Peto data.
So because of that and this being a hazard-based assessment on yes/no rather than concentrations, I deemed this to be obsolete and did not contribute to my decisions and my risk assessment.
Q. Did you read through it?
A. I've read through parts of it as a critique to my understanding that this was used in another deposition, so I read through it to look into it for that reason.
Q. If you could please turn to --

it will not be page 88 in the PDF, but page 88 marked as such in the bottom left-hand corner.
A. All right. Okay. Mine starts at 124.
TRIAL TECHNICIAN: Yeah, same, 125.
MS. BOGDAN: Can you go to page 88?
TRIAL TECHNICIAN: No, it starts at 125.
MS. BOGDAN: Okay. Well, then, we'll go to page 125, which is the Nitrosodimethylamine section, and then from there, if we could go to page -- you just have a different version of this than I have in front of me here, so if we could go to page -- to page 151.
THE WITNESS: I'm on page 151.
BY MS. BOGDAN:
Q. Okay. Do you see the section that starts "Humans"?
A. Yes.

Q. Okay. And the second paragraph, it says: Studies in vitro suggest that NDMA is metabolized by human liver and lung via the same metabolic pathway as in other mammalian species.
Do you see that?
A. I do see that.
Q. It's fuzzy. Okay.
Do you agree that the studies that are available suggest that NDMA is metabolized by humans via the same metabolic pathway as in other mammals?
MS. LOCKARD: Objection to form, vague.
A. As with a lot of information in the IARC monographs, they don't talk about levels at all. Studies in vitro suggest that NDMAs metabolize by human liver and lung by the same metabolic pathway.
That does not mean that there's the same amount of -- same level of metabolism in the lung as there is in the liver. That's not stated here.
///

BY MS. BOGDAN:
Q. I was more interested in asking your opinion -- I'm sorry. I -- I didn't realize you weren't finished.
MS. LOCKARD: Go ahead, Dr. Johnson.
A. Apologies. This is a very vague statement from my perspective.
BY MS. BOGDAN:
Q. I was more interested in your opinion regarding whether in your investigation into this matter you formed any opinion with regard to whether NDMA is metabolized in humans in a similar way as in other mammals.
MS. LOCKARD: Objection, form. There's -- there's no question pending.
A. Can you --
BY MS. BOGDAN:
Q. Do you have an opinion -- do you have an opinion whether NDMA is metabolized in humans in a similar way as other mammals?

Page 290

A. I have an opinion that cytochrome P450 2E1 is able to metabolize NDMA in humans and in other organisms.
Q. And when you say other organisms, is that mammals or some other type of organism?
A. Specific to my report, where I focused on the rodents and the rodent cancer bioassay, then the presence and ability to metabolize NDMA by cytochrome P450 2E1, there is capacity for that in the rodent systems that we used. So in that regard, that's my answer.
Q. So your answer is that in the rodent cancer bioassay testing, that it indicated that the rodents had the ability to metabolize NDMA by the cytokine P450s as NDMA is metabolized by humans?
A. Yes, that was my understanding. And from my analysis and reading around that statement being correct, I'm comfortable with that statement.
And also from my understanding of how these substances -- how NDMA causes

Page 291

mutation and then cancer at certain concentrations is why we can focus on the liver as being the target organ for the highest level of mutation and cancer as seen through the robust cancer bioassay and mutation test systems that I've included in my report. The downstream organs are lesser affected or not affected.
So in that regards, that's my answer.
Q. And that's based upon the information you derived from the rodent bioassays?
A. And also an understanding of the metabolism of the substance. And I'm aware of experts in PK modeling and -- pharmacokinetic modeling and distribution modeling that the analysis presented by such experts are that the substance, including NDMA, would reach the liver and be metabolized by those enzymes in the liver to the highest extent, potentially leaving not very much of that substance to go to downstream organs.

Page 292

That's my understanding from the literature and from reading many different reports from different experts.
Q. Do you have a particular study that you reviewed that you would cite to for the proposition that you just testified to?
A. I'm aware that there's metabolism experts as another -- I was getting feedback. Has something changed? I'm getting feedback.
Q. I heard a little feedback as well. It seems like it's cleared now.
A. Okay. So I'm aware that there's a metabolism expert -- I potentially forgot the name -- but from the GT side that has been in line with this concept that the liver has the highest level of metabolism. I think it's Bottorff, but I may be corrected. And that's in line with my discussions.
Also, because I work very closely with EMA and so forth, I realize all the risk assessments to date have also been on the liver, exactly down to this same issue, this same discussion point that the

Page 293

liver is the most metabolically competent organ for metabolizing this substance.
And with all of that information together, that's where I come to my conclusion.
Q. You testified earlier, I believe, that you had reviewed the other defendants' expert reports; is that correct?
A. Some of them. And I considered them all.
(Clarification requested by the stenographer.)
BY MS. BOGDAN:
Q. Did you consider some of them or consider them all? It was difficult to hear your response, Doctor.
A. Oh, apologies. I've considered them all and assessed some of them.
Q. And what's the difference between considering them and assessing them?
A. My definition as I've just stated, considered would be is the report relevant to my report or to my understanding. If it's something like the epi experts, then

Page 294

that would just be considered and not read in detail.

If it was something more relevant, something like the Hecht report, I would read that in a fine level of detail, or the Panigrahy one, for example, and then that would -- I would carry it out in that way.

Q. Did you rely on, for example -- I think you mentioned Dr. Bottorff's report with regard to the determination that the liver was the target organ?

A. I did not. I made that decision based on the risk assessments to date that were all on the liver, as with all the experts, understand that this is the case for these substances, and from my reanalysis of the in vivo cancer bioassay data as well, for which the liver was always the most sensitive and most important test tissue.

Q. When you reviewed the defendants' expert reports, did you find anything you disagreed with?

MS. LOCKARD: Objection, vague, overbroad.

Page 295

Do you want him to reread them and tell you what he disagrees with or if he agrees with every statement?

MS. BOGDAN: Well, let me ask the question a different way.

BY MS. BOGDAN:

Q. When you reviewed the defendants' expert reports, was there anything you took note of in their report that you disagreed with?

A. I cannot recall.

Q. If we reviewed your list of materials considered, would you be able to tell me which expert reports you assessed?

A. I would not be beyond the previous answer that I gave to this question.

Q. Would you be able to tell me any of the experts by name that you read and assessed their full report?

A. Can you repeat the last half of -- the final sentence, please?

Q. Sure.

I said would you be able to tell me any of the experts by name that you

Page 296

read and assessed their full report?

A. Dr. Hecht, Lagana, Panigrahy. Potentially Etminan, but maybe I'm not so confident. Let me get through.

I've read, I would say Chodosh. And there's been other ones in there, say, aspects of Bottorff, Raphael Nudelman, and I've seen many of the others as well.

But off the top of my head, maybe their names are more memorable. I can agree to those ones.

Q. When -- if we could go back to the exhibit, page 151, that's up on the screen, when you reviewed the older studies, did you find studies in different animal species where NDMA was found to cause cancer?

MS. LOCKARD: Objection, form, vague.

A. I looked at some of these -- I think some of these are listed here -- and the studies contributing to those decisions. I think one of the experts expanded on many of these studies in their report.

So due to that, I looked at

Page 297

those reports to see if the cancer studies within these test systems looked to be of suitable study design, say, were they the right route of exposure, or were they intraperitoneal injections? Were they swimming in crazy -- like very high concentrations of the substance?

Really to see if the test -- if the study design was anything close to the OECD guidelines, which this document, again, predates, to make it so any of these findings were able to contribute to my decision.

And I found issues with all of the study designs that I looked at, mostly based on route of administration, very high concentrations, no dose response. It's also precancer bioassay OECD guideline, which means that not even the animal husbandry, things like that were consistent, preparation of dosing. Basically, nothing can be reliable from such a test.

And that's the kind of considerations that I went through. In considering how incredible datasets such as

Page 298

the Peto dose-response data and those that reside in the cancer potency database for this actual risk assessment are not this preliminary, really issue-based hazard assessment from IARC, then I found many issues in these studies.

BY MS. BOGDAN:

Q. If we could please go to page 152. You see the section that's entitled Evaluation?

A. I can see the section.

Q. Okay. And in that evaluation, which again, was done in 1978 --

A. Yeah.

Q. -- it reads: There is sufficient evidence of carcinogenic effect of N-nitrosodimethylamine in many experimental animals.

A. Based on --

Q. Do you --

MS. LOCKARD: Hold on.

(Simultaneous discussion interrupted by the stenographer.)

///

Page 299

BY MS. BOGDAN:

Q. There's a little bit of a delay. Do you agree with that statement?

A. I believe that that's their statement, but it's based on very flawed experimental designs, predating the cancer bioassay guideline and obsolete to my report, and this is hazard-based too.

Q. Well, the Peto study that you're referencing, which came along later, if I'm remembering, maybe 1991, correct, thereabouts?

A. Yes, correct, thereabouts.

Q. That -- that study provided evidence of a carcinogenic effect of N-nitrosodimethylamine, didn't it?

MS. LOCKARD: Objection, form, vague.

A. It provided carcinogenicity at certain doses in that study in those -- in that test system.

BY MS. BOGDAN:

Q. And then reading on, the statement by IARC back in 1978 was:

Page 300

Similarities in its metabolism by human and rodent tissues have been demonstrated.

And then it reads on: Although no epidemiological data were available -- and then it says -- and efforts should be directed toward this end, N-nitrosodimethylamine should be regarded for practical purposes as if it were carcinogenic to humans.

Was that the guidance that was given by IARC back in 1978?

A. That looks to be the guidance provided by IARC in 1978, but it looks like with their updated definition, that it will be probable human carcinogen.

MS. BOGDAN: Can we please mark the IARC monograph dated 1987.

(Whereupon, Deposition Exhibit Johnson-23, 1987 IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, was marked for identification.)

MS. BOGDAN: Can I have a check on the time?

Page 301

THE STENOGRAPHER: You are at 6 hours, 52.

And this is Exhibit 23.

BY MS. BOGDAN:

Q. Have you reviewed this document or are you familiar with it?

A. Apologies. It's not up yet. Which exhibit again, please?

THE STENOGRAPHER: 23.

THE WITNESS: Yeah, it's still not up for me, apologies. It's appeared now. I'm just loading it.

MS. BOGDAN: Okay.

THE WITNESS: Okay. Here we go. I've got it.

BY MS. BOGDAN:

Q. All right. And, this document, if you can see it, is an IARC monograph as well, and it's an update to the IARC monographs. And this document was produced in 1987.

Can you see that?

A. I can see that, again, predating the Peto study, which is

Page 302

interesting.
Q. Okay. And then are you familiar with the different classifications that IARC has developed for the different chemicals?
A. I am. I'm aware of their hazard-based classifications of these chemicals.
Q. Do you know what IARC has graded NDMA?
MS. LOCKARD: Object to form, vague, misstates the document.
A. My understanding is a probable human carcinogen.
BY MS. BOGDAN:
Q. If we could go to page 31 of this document. And the page numbers are on the upper inside corner.
A. Almost there.
Q. If I could direct your attention to the very last paragraph, which starts with "Group 2A."
A. I'm still finding it. My PDF reader is saying the pages are different.

Page 303

Group 2A, I think I found it.
Q. Okay. I think it's also been put up maybe a little larger on the screen so you can see it.
A. Oh. I'll go with the Zoom screen for this. Thank you.
Q. Is it your understanding that IARC has classified NDMA and NDEA as a Group 2A chemical?
A. It is my understanding that they've classified NDMA and NDEA as probably carcinogenic to humans based on this hazard-based assessment, yes.
Q. Can you read the description that IARC has for the agent is probably carcinogenic to humans?
A. Which sentence --
Q. You can read them all in its entirety.
A. Okay. This category is used when there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals. Exceptionally, an agent may be

Page 304

classified into this category solely on the basis of limited evidence of carcinogenicity in humans or of sufficient evidence of carcinogenicity in experimental animals strengthened by supporting evidence from other relevant data.
Q. And is that your understanding of the 2A classification by IARC for a probable human carcinogen?
A. That is my interpretation of their classification of 2A, a probable human carcinogen, yeah.
Q. If we can go to page 42 of the document, and where it says: Group 2A. The working group concluded that the following agents are probably carcinogenic to humans.
Do you see that?
A. Yes, I see that.
Q. And directing your attention down the list, about seven from the bottom, do you see N-nitrosodiethylamine?
A. Yes, I do.
Q. And N-nitrosodimethylamine?
A. Yes, I do.

Page 305

Q. And this document is classifying them as, if we look at the top, probably carcinogenic to humans, correct?
A. According to their definition of that with no consideration of dose, just in a hazard-based assignment, they're probably carcinogenic to humans, correct, according to their classification.
Q. Okay. Thank you.
MS. BOGDAN: Can we go off the record, please.
THE VIDEOGRAPHER: Going off the record. The time is 5:38 p.m.
(Discussion off the record.)
(Whereupon, the following proceedings were conducted off the videotaped record.)
MS. LOCKARD: So we're back on the record after having taken a break.
I just want to make the record clear that plaintiffs' counsel is stopping the deposition after we've been on the record now for less than 7 hours.

Page 306

It's our expectation that, you know, the option for going into a second day is when it cannot be finished in the first day.

It's only 12:39 p.m. on East Coast time currently, so for the record, we are ready and willing to continue moving forward with the deposition.

We have international flights tomorrow night that we have to make, so if -- you know, if we're going to stop now, I just want to make sure the record is clear we're going to have to plow through tomorrow because we're not changing our flights because we stopped at, you know, 12:30 on Eastern Time.

MS. BOGDAN: And just so the record is clear, we began this deposition at 4:00 a.m. Eastern Time, so we have been at this over 8, almost 9 hours, and had to, obviously, get up and be here.

Page 307

Victoria, I don't know what time your flights are tomorrow. We noticed the deposition for two days.

And we have done -- when you say under 7 hours of record time, well, 6 hours and 58 minutes is, in my opinion, about 7 hours of record time.

So I don't understand why there would be any reason that we could not start at, again, 4:00 a.m. Eastern Standard Time tomorrow and continue to take the deposition.

I don't know what time your flights are, but, you know, given the fact that this is a two-day deposition, I just don't think that's a justification for not being able to conclude this.

THE STENOGRAPHER: Anything else?

MS. LOCKARD: Yeah.

The only other thing I'm saying is if we're stopping now, tomorrow, if we're starting in the morning at 9:00,

Page 308

we're not going to have time for breaks. We're going to have to go -- I mean, very short breaks, but we're going to have to go through.

MS. BOGDAN: What time is your flight tomorrow?

MS. LOCKARD: He's got to leave for the airport, my colleague, at 2:00 to make the flight.

So, I mean, we assumed that we would push through today and get there, you know, do the last bit tomorrow. But if we're -- if you're taking 10 hours on the record, I just want to be clear, we're not going to push late tomorrow, so...

MS. GOLDENBERG: I mean, that's 3 hours of testimony in 5 hours of time. I think we should be okay.

MS. LOCKARD: Well, I'm just making our position known so there's no dispute about it tomorrow. And we'll start tomorrow at the same time.

THE STENOGRAPHER: Anything

Page 309

else for the record?

MS. BOGDAN: Did Marlene's statement get on the record? Because I was going to say the same thing.

MS. LOCKARD: It did. It's on the record.

I mean, obviously, I'm going to have questioning too, so -- but we can go off the record. We'll start at 9:00 a.m. tomorrow.

THE STENOGRAPHER: Off the record.

(Time noted: 5:43 p.m. BST)

--o0o--

CERTIFICATE

I, MICHAEL E. MILLER, Fellow of the Academy of Professional Reporters, Registered Diplomate Reporter, Certified Realtime Reporter, Certified Court Reporter and Notary Public, do hereby certify that prior to the commencement of the examination, GEORGE JOHNSON, Ph.D. was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that pursuant to FRCP Rule 30, signature of the witness was not requested by the witness or other party before the conclusion of the deposition.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

____

MICHAEL E. MILLER, FAPR, RDR, CRR
Fellow of the Academy of Professional Reporters
NCRA Registered Diplomate Reporter
NCRA Certified Realtime Reporter
Certified Court Reporter

New Jersey Certified Court Reporter
No. 30XI00242200
Expires: 6/30/2022

Dated: October 18, 2021

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ERRATA

PAGE LINE CHANGE

____ ____ ____________________________
REASON: ____________________________
____ ____ ____________________________
REASON: ____________________________
____ ____ ____________________________
REASON: ____________________________
____ ____ ____________________________
REASON: ____________________________
____ ____ ____________________________
REASON: ____________________________
____ ____ ____________________________
REASON: ____________________________
____ ____ ____________________________
REASON: ____________________________
____ ____ ____________________________
REASON: ____________________________
____ ____ ____________________________
REASON: ____________________________
____ ____ ____________________________
REASON: ____________________________
____ ____ ____________________________
REASON: ____________________________

ACKNOWLEDGMENT OF DEPONENT

I, GEORGE JOHNSON, Ph.D., do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
GEORGE JOHNSON, Ph.D. DATE

Subscribed and sworn to before me this
_______ day of _______________, 20 _____.
My commission expires: _______________

____
Notary Public

LAWYER'S NOTES

PAGE	LINE	

WORD INDEX

Errata Sheet

October 4-5, 2021 Deposition Transcript – George Johnson, Ph.D.
In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation

MONDAY 10/4/21

Pages, Lines	Change:	Reason
64:24	Change "test" to "**testing**"	Clarification
83:23	Change "I've" to "**I**"	Clarification
94:10	Change "how it's occurred" to "**how it occurs**"	Clarification
157:23	Change "slide date" to "slide **deck**"	Clarification.
174:13	Change "replied" to "**replying**"	Clarification
192:6-7	"or if, as we predicted, the observed concentration would be below the PDE…"	Clarification
199:23	Change "contour" to "**quantal**"	Transcription error
205:12	Change "covariant" to "**covariate**"	Transcription error
219:17	Change "was" to "**were**"	Transcription error / Correction
258:20	"I did, (as in "what I did was")" – should edit to say, "What I did was, I looked at ….	Transcription error / Correction

TUESDAY 10/5/21

Pages, Lines	Change:	Reason
328:2	Add: "and even then it will not be 100% pure."	Completeness / clarification
340:22	Change "multiples suggested" to read "multiple ***species***" suggested by….	Transcription error / clarification.
351:11-13	Remove names; incorrect recollection, these persons not involved.	Correction
377:11-12	Change "lie to" and make it "**align with**"	Transcription error / correct testimony
379:3	Change "far" to "**for**"	Transcription error / correct testimony
381:6	Insert "**do not**" before have	Transcription error / correct testimony
384:5	Change 1-100 risk to **1-100,000**	Transcription error / correct testimony
384:6	Change 1-100 risk to **1-100,000**	Transcription error / correct testimony
387:1-2	Edit "That's the background" to "**That's the actual background rate of cancer.**"	Completeness and clarification
421:3	Delete "would be"	Correction / Clarification
445:20	Change "antigens" to "**aneugens**"	Transcription error / correct testimony

446:21	Change "vice president" to "**past president**"	Transcription error / correct testimony
460:1	Change "is it shows" to "is **that** it shows"	Clarification
463:12	Strike "I do"	Clarification
492:6	Change "talking" to "**talk**"	clarification
495:21	Change "To say" to "**For example**"	Clarification
507:13	Change "yeah" to "**yes**"	Proper English
518:24	Add comma after "would be**,**"	Clarification on sentence

George Johnson, Ph.D.

K Harris, Notary Public.

This, the 17th day of November, 2021.

My Commission Expires: Kimberly Harris NOTARY PUBLIC Forsyth County, GEORGIA My Commission Expires February 6, 2024.